COLLABORATION AND SUBGRANT AGREEMENT

for a Collaborative Project

Project full title: “Effects of Advanced Trauma Life Support® Training Compared to Standard Care on Adult Trauma Patient Outcomes (ADVANCE TRAUMA): A Cluster Randomised Trial”

Project Leader: Karolinska Institutet
(Martin Gerdin Wärnberg)

THIS COLLABORATION AND SUBGRANT AGREEMENT IS EFFECTIVE FROM ON 01-01-2024, HEREINAFTER REFERRED TO AS THE "EFFECTIVE DATE BETWEEN:

1. **Karolinska Institutet**, Department of Global Public Health, Nobels väg 6, 171 77, Stockholm, Sweden, org.nr 202100-2373 ("KI" or "Project Leader"), and

2. **George Institute for Global Health**, with its office at 308 Elegance Tower, Plot No. 8, Jasola District Centre, New Delhi 110025, India and company identification number U74900TG2007NPL055085 ("TGI" or "Study Coordinator")

hereinafter, jointly or individually, referred to as "Parties" or "Party".

WHEREAS:

A. The Parties have a mutual interest in achieving research results regarding the project entitled "Effects of Advanced Trauma Life Support® Training Compared to Standard Care on Adult Trauma Patient Outcomes (ADVANCE TRAUMA): A Cluster Randomised Trial", (the "Project").

B. KI has obtained grants from the Swedish Research Council (Vetenskapsrådet), and from the Laerdal Foundation, hereinafter referred to as the "Funding Entities" to conduct the Project, (hereinafter the "Research Grant").

C. The Parties wish to collaborate with KI to implement the Project and have therefore entered into this collaboration and subgrant agreement (hereinafter the "Agreement") for the purpose of setting out the terms and conditions of the collaboration.

NOW, THEREFORE, IT IS HEREBY AGREED AS FOLLOWS:

1 DEFINITIONS

Words beginning with a capital letter shall have the meaning defined herein.

"Access Rights" means user rights to Background or Results.

"Background" means any data, know-how or information which is held by the Parties prior to their accession to this Agreement, as well as copyrights or other intellectual property rights pertaining to such information, the application for which has been filed before their accession to this Agreement and which is needed for carrying out the Project or for Use of the Results.

"**Data**" means the data collected in India under the scope of the Trial.

"Exploitation" means the direct or indirect utilisation of Results, in particular through transfer or licensing by using them in further research activities other than those covered by the Project, or for developing, creating and marketing a product or process, or for creating and providing a service.

"**Funding Entity/ies**" means the organisation providing funding of the Project, in this case the Swedish Research Council (*Vetenskapsrådet*) and the Laerdal Foundation.

"Individual Result" means a Result which a Party can demonstrate has been generated solely by such Party or independently of any collaboration with the other Party.

"Needed" means:

(a) for the implementation of the Project: Access Rights are Needed if, without the grant of such Access Rights, carrying out the Project related tasks by the recipient Party would be impossible, significantly delayed, or require significant additional financial or human resources.

(b) for Use of own Results: Access Rights are Needed if, without the grant of such Access Rights, the Use of own Results would be technically or legally impossible.

"Personal Data" means any information relating to an identified or identifiable natural person ('data subject'); as this term is defined under Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation, hereinafter "GDPR").

"Project Leader" means KI, the recipient of the Research Grant that is responsible for the administration of the Research Grant, the planning and implementation of activities according to the application approved by the Funding Entities.

"Project Plan" means the Protocol as first defined in Schedule 1.

"**Protocol**" means the description of the Trial developed jointly by KI and TGI, and all amendments thereto as the Parties may from time to time agree. Such amendments will form an integral part of this Agreement.

"Results" means any tangible or intangible output of the Project such as data, knowledge or information, whatever its form or nature, whether it can be protected or not, that is generated under the Project, as well as any rights attached to it, including intellectual property rights.

"Study Coordinator" means TGI as the organization responsible for the initiation, coordination and management of the Trial in India in accordance with applicable national laws, GCP and the Protocol.

"**Study Site**" means any hospital or clinic in India involved by TGI in the conduct of the Trial under TGI's responsibility.

"**Subject**" means a person recruited to participate in the Trial.

"Trial" means the academic driven, multicentre, prospective cluster randomized clinical trial of Advanced Trauma Life Support compared to standard care (clinicaltrials.gov NCT05417243) conducted by TGI in India pursuant to this Agreement.

Any reference to a statutory provision, code or guidance shall be deemed to include reference to any statutory modification or re-enactment of it.

2 PURPOSE

The purpose of this Agreement is to specify with respect to the Project the relationship among the Parties, in particular concerning the organisation of the work between the Parties, the management of the Project and the rights and obligations of the Parties concerning inter alia liability, intellectual property rights and dispute resolution.

3 DURATION AND TERMINATION

3.1 This Agreement shall have effect from the Effective Date identified at the beginning of this Agreement and shall continue in full force and effect until 31 December 2029 or until complete fulfilment of all obligations undertaken by the Parties under this Agreement. However, this Agreement may be terminated earlier in accordance with the terms of this Agreement and the General Terms and Conditions of the Research Grant as included in Schedule 2 of this Agreement. If a Party does not obtain all necessary approvals for the Project from relevant authorities, this Agreement shall be terminated as soon as practicable with due consideration to patient safety and research matters.

3.2 The provisions relating to Results and Intellectual Property, Confidentiality for the time period mentioned therein, as well as for Liability, Applicable law and Settlement of Disputes shall survive the expiration or termination of this Agreement.

4 RESPONSIBILITIES OF THE PARTIES

4.1 General principles

4.1.1 Each Party undertakes to take part in the efficient implementation of the Project, and to cooperate, perform and fulfil, promptly and on time, all of its obligations under this Agreement in accordance with the terms of the Research Grant as included in Schedule 2 of this Agreement and in a manner of good faith.

4.1.2 Each Party undertakes to notify promptly to the Project Leader any significant information, fact, problem or delay likely to affect the Project. Each Party shall carry out its responsibilities in accordance with the Project Plan and shall bear sole responsibility for ensuring that its acts within the Project do not knowingly infringe third party property rights.

4.1.3 Each Party shall promptly provide all information reasonably required by any of the other Party to carry out its tasks and shall take reasonable measures to ensure the accuracy of any information or materials it supplies to the other Party.

4.1.4 Each Party shall ensure that its work on the Project complies fully with all applicable local, government and international laws, regulations and guidelines which are effective during the period of the Research Grant, including those governing health and safety, data protection, and where relevant, the use of human or animal subjects and good clinical practice. In this regard, each Party shall maintain the confidentiality, in accordance with the applicable laws, regulations and guidelines, of all samples and data relating to the use of human subjects, which is created or used in the course of the Project.

4.1.5 Each Party shall secure all necessary approvals from the relevant research ethics committees before undertaking any part of the Project requiring ethics committee approval and shall, if required, obtain properly signed informed consent and acknowledgement forms from any human subjects, or their legal guardians, who they will involve in the Project.

4.1.6 Each Party shall handle the Project documentation in a manner acceptable for the collection of data for submission to or review by, a regulatory authority and in full compliance with the Protocol and all applicable laws and regulations (which includes Good Clinical Practice).

4.2 Breach

In the event that a Party is in breach of its obligations under this Agreement (e.g. improper implementation of the Project), the Project Leader will give formal notice to such Party requiring that such breach be remedied within a reasonable time frame after the notice. The Project Leader shall report the breach to the Funding Entities who may decide on the consequences thereof which may include suspension or termination of the Project.

4.3 Involvement of third parties

A Party that enters into a subcontract or otherwise involves third parties in the Project remains solely responsible for carrying out its relevant part of the Project and for such third party's compliance with the provisions of this Agreement, including the Protocol. Such Party has to ensure that the involvement of third parties does not affect the rights and obligations of the other Party under this Agreement.

4.4 Specific responsibilities of the Parties

4.4.1 Karolinska Institutet (KI)

KI will be responsible for distributing the Research Grant, in line with the approved budget, as further stated in Section 7 and schedule 3.

KI as the Project Leader of the Project will be responsible for:

a) the design of the Trial in collaboration with TGI;

b) the conduct of statistical analysis of Data and the interpretation of findings in collaboration with University of Birmingham (Karla Hemming);
c) coordination and drafting of publications;
d) preparation of dissemination messages in collaboration with the other Party;
e) compliance with Swedish laws and regulations related to storage of data;
f) registration of the Trial and reporting of results in www.clinicaltrials.org; and
g) signing up a separate collaboration agreement with the University of Birmingham to enable their participation in the Project in the form of expertise and know-how regarding the design of Data analysis and their contribution to publications and dissemination messages in collaboration with KI and TGI.

4.4.2 George Institute for Global Health (TGI)

TGI shall be the Study Coordinator responsible for the execution, coordination and management of the Trial in India. TGI shall assume all legal responsibilities for the implementation of the Trial in India in accordance with Good Clinical practice.

As Study Coordinator, TGI will be solely responsible for:

a) the design of the Trial in collaboration with KI and the direction and management of the Trial in India;
b) translating the Protocol and additional documentation, including Subject documents and informed consent forms into local language, as appropriate;
c) engaging Study Sites and any subcontractors and liaising with them and providing them all necessary information to ensure that the Trial is conducted in accordance with the Protocol, GCP and applicable laws;
d) entering into appropriate written agreements with the Study Sites for the conduct of the Trial, in accordance with applicable laws, to ensure recruitment of Subjects and collection of Data,;
e) monitoring the Trial;
f) conducting training,
g) collecting, documenting and reporting patient data and reporting serious adverse events;
h) ensuring Data quality;
i) Data storage;
j) reporting serious breaches;
k) any coordinating activities in accordance with the Protocol;
l) being a contact point for receiving all questions from Subjects, Principal Investigators and national regulatory authorities regarding the Trial and providing answers to them;
m) contributing to analyses, interpretation of findings; and
n) contributing to drafting publications and shaping dissemination messages in collaboration with KI and with University of Birmingham.

TGI shall secure all necessary approvals from the relevant research ethics committees in India and for registering the Trial, including any amendments thereof, with the relevant authorities in India before undertaking any part of the Trial. TGI shall obtain properly signed informed consent and acknowledgement forms from any Subjects who they involve in the Project. TGI shall ensure that all necessary approvals, indemnities and agreements from Study Sites involved are obtained.

TGI shall remain fully and directly liable for its own activities and for its compliance with applicable laws. TGI shall obtain and maintain complete and relevant insurances, including patient insurance, as required by applicable laws and shall if required provide KI with a certificate to such effect.

4.5 Personal data

4.5.1 Each Party shall maintain the confidentiality, in accordance with the applicable laws, regulations and guidelines, of all samples and personal data (including digital and paper data) relating to the use of human subjects, which is created or used in the course of the Project and shall ensure that all local communities, hospitals and primary health facilities involved in the Project comply with said obligations and any further instructions and security measures to ensure personal data is processed as required by applicable laws.

4.5.2 TGI shall ensure that documentation and collection of Data in the Trial is made in full compliance with the Protocol and all applicable laws and regulations, including GCP and that the collection of Data is conducted in a manner which provides for the correct submission to, or review by, relevant regulatory authorities.

4.5.3 The Parties acknowledge and agree that in relation to the Data (Personal Data) collected by TGI under and in connection with the Study, the Parties KI and TGI are joint controllers pursuant to Article 26 GDPR and their respective responsibilities will be agreed upon in the separate Joint Controller Agreement to be signed by KI and TGI.

4.5.4 In respect of Personal Data collected by TGI under and in connection with the Trial, TGI shall (i) comply with any applicable data protection laws; (ii) use reasonable endeavours to ensure that all Personal Data is processed lawfully, fairly and in a transparent manner and in compliance with the data protection laws to which it is subject; (iii) enter into such other written agreements with third parties, including Study Sites as may be required from time to time to enable the processing of Personal Data by the Parties.

5 LIABILITY

5.1 No warranties

In respect of any information or materials (including Results and Background) supplied by one Party to another under the Project, no warranty or representation of any kind is made, given or implied as to the sufficiency or fitness for purpose nor as to the absence of any infringement of any proprietary rights of third parties.

Therefore, the recipient Party shall in all cases be entirely and solely liable for the use to which it puts such information and materials, and no Party shall be liable in case of infringement of proprietary rights of a third party resulting from any other Party (or its affiliated entities) exercising its Access Rights.

5.2 Limitations of contractual liability

No Party shall be liable to the other Party for any indirect or consequential loss or similar damage such as, but not limited to, loss of profit, loss of revenue, loss of contracts or any other indirect loss.

Notwithstanding anything contained in this Agreement, a Party's aggregate liability towards the other Party shall be limited to 50 000 Euro, provided such damage was not caused by a wilful act or gross negligence.

TGI shall solely be liable for any claims and proceedings made or brought by or on behalf of Subjects or Study Sites against the Parties for personal injury to Subjects to the extent arising out of or relating to the conduct of the Study in accordance with this Agreement and the applicable Protocol (and any amendments thereto).TGI shall maintain clinical trial liability insurance in respect of its obligations to third parties and sufficient limits to cover the indemnification obligations in this Agreement, and the cost of such insurance will be included in the budget for the Project as specified in the financial plan, Schedule 3 of this Agreement.

The terms of this Agreement shall not be construed to amend or limit any Party's statutory liability.

5.3 Damage caused to third parties

Each Party shall be solely liable for any loss, damage or injury to third parties resulting from its performance under this Agreement or from its use of Results or Background.

5.4 Force Majeure

No Party shall be considered to be in breach of this Agreement if it is prevented from fulfilling its obligations under the Agreement by Force Majeure, i.e. any unforeseeable, exceptional situation or event which is beyond the reasonable control of a Party. Each Party will notify KI of any Force Majeure without undue delay.

6 IMPLEMENTATION

6.1 Each Party shall designate a responsible principal investigator (PI) who shall be responsible for all activities undertaken by the respective Party pursuant to this Agreement and shall supervise and lead the work as well coordinate the specific activities agreed upon. The PI shall serve as the primary contact for each Party. PIs at the time of signature of this Agreement are:

- Martin Gerdin Wärnberg at KI
- Vivekanand Jha at TGI

The Parties may invite Karla Hemming of the University of Birmingham to the meetings when considered relevant.

6.2 The Parties shall have regular contact to discuss the progress of the Project. The Project Leader shall convene ordinary follow-up meetings at least once a year and extraordinary meetings at any time upon written request by another Party.

The Project Leader shall be the intermediary between the Parties and the Funding Entities and shall perform all tasks assigned to it as described in this Agreement. In particular, the Project Leader shall be responsible for:

(a) monitoring compliance by the Parties with their obligations in accordance with the Research Grant;
(b) monitoring scientific implementation of the Project in accordance with the Project Plan;
(c) transmitting documents and information connected with the Project;
(d) administering the financial contribution of the Funding Entities and fulfilling the financial tasks described in Article 7.3; and
(e) preparing and submitting scientific and financial reports in accordance with the Funding Entities' instructions.

6.3 The Project Leader shall not be entitled to act or to make legally binding declarations on behalf of TGI, unless explicitly stated otherwise in the Research Grant or this Agreement.

7 FINANCIAL PROVISIONS

7.1 General Principles

7.1.1 Distribution of the Financial Contribution

7.1.1.1 TGI shall be funded only for its activities/tasks carried out in accordance with the Project Plan during the period specified in the Research Grant, (hereinafter referred to as "Grant Period"), in compliance with the Project Plan and in accordance with the General Terms and Conditions of the Research Grant as included in Schedule 2 of this Agreement up to the maximum amount specified in Schedule 3.

7.1.1.2 Payments shall be made in accordance with the payment plan specified in Schedule 4. KI assumes no obligation to provide funds in excess of the maximum total amount indicated

in Schedule 3. Any increase in the authorized total must be mutually agreed upon in writing by the Parties. Any significant changes concerning the agreed budget are subject to approval by KI following an amendment as agreed in Section 10.4.

7.1.1.3 The Research Grant shall be used in the manner specified in the Project Plan. Any significant changes concerning the Research Grant's use are subject to approval by the Funding Entities following a review.

7.1.1.4 TGI shall notify KI if a grant is offered or received from another funding body for the same or similar research during the Project. This notification must specifically indicate the extent to which another funding body could influence the implementation, analysis, interpretation and reporting of the Results.

7.1.2 Record Keeping

In accordance with its own usual accounting and management principles and practices, each Party shall be solely responsible for justifying its costs with respect to the Project towards the Funding Entities.

The Parties agree to collaborate and enable the audit of financial records and accounts associated with the Project by an auditor or equivalent appointed by the Funding Entities.

7.1.3 Financial Consequences for premature termination of the Project

In the event of premature termination of the Project, for which both parties shall provide 90 days written notice to the other party, each party shall refund the payments received under the Research Grant as required by the Funding Entities, after adjusting for all actual costs until the termination date.

7.2 Payments

7.2.1 Payments shall be made in SEK according to the payment plan in Schedule 4. The Project Leader shall incur no liability to TGI in the event that, for any reason not attributable the Project Leader's fault, any payment to KI, which would otherwise have been payable shall be withheld, delayed or adjusted by the Funding Entities. KI's sole financial obligation under this Agreement shall be to forward the payments allocated to TGI under the budget in Schedule 3.

7.2.2 Grant Payment requests (hereinafter called Invoices for convenience) shall be submitted to KI and will be payable within 30 days of receipt. The invoices shall contain a specification of the activities to be carried out and a specification of the costs to be covered. KI will not accept invoices relating to activities not described or specified in the invoice.

TGI shall submit invoices according to the payment schedule as mentioned in Schedule 4. TGI shall upon request be able to show documentation in support of a certain invoice phase having been attained. Such documentation shall include necessary receipts and documentation concerning the costs. Invoicing charges are not acceptable.

The invoices shall include a clear reference to this Agreement including its contract nr and clearly state the period for which payment is made, information about whether partial or full payment.

Invoices shall be sent as a PDF-file (one file per invoice) to the following e-mail address: KI-fakturor@ki.se.

7.2.4 The Project Leader is entitled to withhold any payments due to a Party in breach of its obligations under this Agreement or when this is agreed with the Funding Entities. The Project Leader is entitled to recover any payments already paid to a defaulting Party.

7.3 Reporting

TGI shall collaborate with KI to enable the timely submission of any scientific and financial reports concerning the Project which may be requested by the Funding Entities and shall provide any necessary information in conjunction with the following up and evaluation of the research, either during or after termination of the Project.

The Parties shall also collaborate in order for KI to submit a final financial statement report every year, no later than one months after the Grant Period has expired.

In particular, each Party shall provide the Project Leader with all the information and documentation which needs to be included in the final financial report not later than one month after the Grant Period has expired or not later than one month after the date of premature termination of the Project.

TGI shall collaborate to enable the audit by KI of and financial records, accounts and documentation regarding the conduct of the Project and fulfilment of obligations by TGI.

8 RESULTS

8.1 Background

Background is, and shall remain, the property of the contributing Party, and may, during the term of the Agreement and without compensation, be used solely for the purpose of performing the Project. Other than expressly stated herein, this Agreement does not constitute any grant, option or license under the Background held by either Party.

8.2 Ownership of Results

Results are owned by the Party and/or by the researcher of the Party (if applicable) that generate them pursuant to each Party's national laws and policies on intellectual property. Title to any Results owned by KI which consist of intellectual property rights shall vest in the KI researchers where applicable in accordance with the Swedish professor's privilege.

Where Results are jointly generated by more than one Party and/or their researcher(s), such Results will be jointly owned in proportion to their intellectual contribution. In case of joint ownership each of the joint owners shall be entitled to use their jointly owned Results for non-commercial research activities on a royalty-free basis, and without requiring the prior consent of the other joint owner(s).

8.3 Access Rights

8.3.1 Parties are committed to public benefit and shall make Data and Results widely and freely available to maximise the benefits arising from research for non-commercial research, education and training purposes. The Parties commit to making the Data available in open access databases, such as Zenodo and GitHub, in accordance with open data rules and the FAIR (Findable, Accessible, Interoperable, and Reusable) principles. Parties shall be allowed to use Data and Results for the purpose of performing the Project.

8.3.2 Access Rights to Results and Background if Needed for Exploitation of a Party's own Results shall be granted on Fair and Reasonable conditions.

8.3.3 For the avoidance of doubt any grant of Access Rights not covered by the Research Grant or this Agreement shall be at the absolute discretion of the owning Party and subject to such terms and conditions as may be agreed between the owning and receiving Parties. The Research Grant funds are provided under this Agreement to carry out the Project and do not include financial consideration for any Access Rights.

8.4 Publications

8.4.1 Publication of own Results

8.4.1.1 The Parties agree that Results will be published in scientific journals with international scope in collaboration with University of Birmingham. The Parties shall not enter into agreements with any commercial actor or other stakeholder that could limit publication of the Results of research conducted with funding from the Swedish Research Council.

8.4.1.2 The Parties agree that the Results from the Project hereunder will be jointly published, in consistency with academic standards and with due consideration to the protection of intellectual property rights and applicable guidelines. The first publication will be prepared after Data analysis is available. TGI shall ensure that no publications by any individual Principal Investigator at Study Sites will be made, unless approved in advance by the Parties. The Parties agree to abide by the policies of journals in which publications will appear as to such matters as the public release or availability of data relating to the publication.

8.4.1.3 Authorship on publications will be based on academic standards and custom.
In accordance with normal academic practice, all investigators and contributors to a publication will be acknowledged, always in compliance with recognized standards concerning publication and authorship, including the most recent "Recommendations for the Conduct, Reporting, Editing and Publications of Scholarly Work in Medical Journals" developed by the International Committee of Medical Journal Editors (ICMJE). For clarity, researchers from the University of Birmingham will be included in the publications based on their contributions.

8.4.1.4 The Parties agree that research findings from the Project shall be made openly accessible (open access) within six (6) months of publications.

8.4.2 Dissemination of another Party's unpublished Results or Background

A Party shall not include in any dissemination activity another Party's Results or Background without obtaining the owning Party's prior written approval, unless they are already published.

8.4.3 Cooperation obligation

The Parties undertake to cooperate to allow the timely submission, examination, publication and defence of any dissertation or thesis for a degree which includes their Results or Background subject to the confidentiality and publication provisions agreed in this Agreement.

8.4.4 Use of names, logos or trademarks

Nothing in this Agreement shall be construed as conferring rights to use in advertising, publicity or otherwise the name of the Parties or any of their logos or trademarks without their prior written approval.

Publications and dissemination of the Project's Results shall include acknowledgement to the Swedish Research Council and the Laerdal Foundation as further specified in the Research Grant as included in Schedule 2 of this Agreement.

9 NON-DISCLOSURE OF INFORMATION

9.1 All information in whatever form or mode of communication, which is disclosed by a Party (the "Disclosing Party") to any other Party (the "Recipient") in connection with the Project during its implementation and which has been explicitly marked as "confidential" at the time of disclosure, or when disclosed orally has been identified as confidential at the time of disclosure and has been confirmed and designated in writing within 15 calendar days from oral disclosure at the latest as confidential information by the Disclosing Party, is "Confidential Information".

9.2 The Recipients hereby undertake in addition and without prejudice to any commitment of non-

disclosure under the Research Grant, for a period of 4 years after the end of the Project:

(a) to ensure that internal distribution of Confidential Information by a Recipient shall take place on a strict need-to-know basis; and
(b) not to use Confidential Information otherwise than for the purpose for which it was disclosed
(c) not to disclose Confidential Information to any third party without the prior written consent by the Disclosing Party; and
(d) to return to the Disclosing Party on demand all Confidential Information which has been supplied to or acquired by the Recipients including all copies thereof and to delete all information stored in a machine readable form. The Recipients may keep a copy to the extent it is required to keep, archive or store such Confidential Information because of compliance with applicable laws and regulations or for the proof of on-going obligations.

9.3 The Recipients shall be responsible for the fulfilment of the above obligations on the part of their employees or third parties involved in the Project (including the University of Birmingham) and shall ensure that they remain so obliged, as far as legally possible, during and after the end of the Project and/or after the termination of the contractual relationship with the employee or third party.

9.4 The above shall not apply for disclosure or use of Confidential Information, if and in so far as the Recipient can show that:

a) the Confidential Information becomes publicly available by means other than a breach of the Recipient's confidentiality obligations;
b) the Disclosing Party subsequently informs the Recipient that the Confidential Information is no longer confidential;
c) the Confidential Information is communicated to the Recipient without any obligation of confidence by a third party who is to the best knowledge of the Recipient in lawful possession thereof and under no obligation of confidence to the Disclosing Party;
d) the disclosure or communication of the Confidential Information is foreseen by provisions of the Research Grant;
e) the Confidential Information, at any time, was developed by the Recipient completely independently of any such disclosure by the Disclosing Party; or
f) the Confidential Information was already known to the Recipient prior to disclosure or
g) the Recipient is required to disclose the Confidential Information in order to comply with applicable laws or regulations or with a court or administrative order.

9.5 The Recipient shall apply the same degree of care with regard to the Confidential Information disclosed within the scope of the Project as with its own confidential and/or proprietary information, but in no case less than reasonable care.

9.6 Each Party shall promptly advise the other Party in writing of any unauthorised disclosure, misappropriation or misuse of Confidential Information after it becomes aware of such unauthorised disclosure, misappropriation or misuse.

9.7 For the avoidance of doubt, Personal Data shall always be treated as confidential and shall be protected with an adequate level of safety and confidentiality, subject to any applicable legal, regulatory or contractual requirements.

10 MISCELLANEOUS

10.1 Attachments, inconsistencies and severability

10.1.1 This Agreement consists of this core text and
Schedule 1 (Project Plan, Financial Plan and Payment Plan)

Schedule 2 (General Terms and Conditions for Research Grants)
Schedule 3 (Financial plan)
Schedule 4 (Payment plan)

10.1.2 In case the terms of this Agreement are in conflict with the terms of the Research Grant as included in Schedule 2, the terms of the latter shall prevail.

10.1.3 Should any provision of this Agreement become invalid, illegal or unenforceable, it shall not affect the validity of the remaining provisions of this Agreement. In such a case, the Parties concerned shall be entitled to request that a valid and practicable provision be negotiated which fulfils the purpose of the original provision.

10.2 No representation, partnership or agency

No Party shall be entitled to act or to make legally binding declarations on behalf of any other Party. Nothing in this Agreement shall be deemed to constitute a joint venture, agency, partnership, interest grouping or any other kind of formal business grouping or entity between the Parties.

10.3 Notices and other communication

11.3.1 Formal notices to be given under this Agreement shall be in writing and be delivered to the person stated below, unless the receiving Party has specifically notified the sending Party of another address for this purpose. The notice may either be served personally or sent by mail with recorded delivery or telefax with receipt acknowledgement.

To KI: Therese Lind (therese.lind@ki.se)

To TGI: Vivekanand Jha (vjha@georgeinstitute.org.in) with cc to Amit Khanna (akhanna@georgeinstitute.org.in)

11.3.2 Other communication between the Parties may also be effected by other means such as e-mail with acknowledgement of receipt, which fulfils the conditions of written form.

10.4 Assignment and amendments

11.4.1 No rights or obligations of the Parties arising from this Agreement may be assigned or transferred, in whole or in part, to any third party without the other Party' prior formal approval.

11.4.2 Amendments and modifications to the text of this Agreement require a separate written agreement to be signed between all Parties.

10.5 Mandatory statutory law

Nothing in this Agreement shall be deemed to require a Party to breach any mandatory statutory law under which the Party is operating.

10.6 Language

This Agreement is drawn up in English, which language shall govern all documents, notices, meetings, arbitral proceedings and processes relative thereto.

10.7 Applicable law and Settlement of Disputes

10.7.1 This Agreement shall be construed in accordance with and governed by the laws of Sweden excluding its conflict of law provisions.

10.7.2 The parties shall endeavour to settle their disputes amicably. However, where a conflict cannot be resolved within ten working days by persons at an operative level, a Party may request that negotiations be initiated between persons on executive management level.

11 SIGNATURES

AS WITNESS:
The Parties have caused this Agreement to be duly signed, using electronic signatures or otherwise, by the undersigned authorised representatives in separate signature pages the day and year first above written.

KAROLINSKA INSTITUTET

Date:

Signature _____
Name Marie Hasselberg
Title Head of Department

I acknowledge that I have read and agree to be bound by the above terms and conditions and I undertake to ensure that all personnel working in the Project will be aware of and accept all terms and conditions of this agreement.

Signature _____
Name Martin Gerdin Wärnberg
Title Principal Investigator
Department of Global Publich Health

GEORGE INSTITUTE FOR GLOBAL HEALTH (TGI)
Date:

Signature _____
Name
Title

Signature _____
Name
Title

SCHEDULE 1: PROJECT PLAN

SCHEDULE 2: RESEARCH GRANT

Decision of the Swedish Research Council and the applicable General Terms and Conditions for Research Grants applicable to the Project.

Vetenskapsrådet (Swedish Research Council) General Terms and Conditions

The Swedish Research Council's general terms and conditions for funding awarded to research and research-supporting activities

The terms and conditions were adopted by the Swedish Research Council on 19 December 2022. The terms and conditions apply for decisions to award funding made as from 1 January 2023. The terms and conditions shall be applied unless otherwise follows from the decision to award funding or from specific terms and conditions. In the event of a conflict between the general terms and conditions and specific terms and conditions issued for a decision, the specific terms and conditions shall take precedence.

Definitions

In these terms and conditions, the following definitions are used with the meaning stated below.

Administrating organisation

A legal entity approved by the Swedish Research Council as a recipient of research funding awarded.

Applicant

A physical person (project leader) or legal entity who has applied for funding from the Swedish Research Council and is responsible for planning and implementing activities according to the approved application.

Activities

The research or research-supporting activities covered by the Swedish Research Council's decision to award funding

Terms and conditions

These general terms and conditions and the specific terms and conditions that follow from a decision or call text.

1. About the Swedish Research Council's decisions and terms and conditions

1.1 Approval of terms and conditions

The Swedish Research Council's decision to award funding applies on condition that the administrating organisation and applicant agree to the terms and conditions according to the Swedish Research Council's instructions.

1.2 Responsibility to comply with terms and conditions

The administrating organisation and applicant are responsible for complying with the terms and conditions. If the administrating organisation is also the applicant, the administrating organisation is responsible for complying with the terms and conditions in both these capacities.

1.3 Period of validity of terms and conditions

The terms and conditions are valid as from their approval up to and including the date when final reports have been received by the Swedish Research Council or, as applicable, unused funds have been repaid and the case has been closed.

1.4 Changed preconditions for the Swedish Research Council's funding allocation
The Swedish Research Council may change its decision to award funding if the Swedish Research Council's Government appropriation is not as large as the amount the decision was based on, or if the preconditions for the Swedish Research Council's allocation of funding is changed in some other way.

2. Implementation

2.1 Implementation according to the decision and the terms and conditions
The administrating organisation and applicant are responsible for ensuring activities are implemented according to the Swedish Research Council's decision and the terms and conditions.

2.2 Implementation according to legislation as applicable in Sweden
The administrating organisation and applicant are responsible for ensuring activities are implemented according to legislation as applicable in Sweden.

2.3 Implementation according to the application
The applicant is responsible for ensuring activities are implemented as described in the application to Swedish Research Council. The responsibility includes planning and conducting activities mainly according to the application and plan for implementation submitted. Necessary changes to the implementation are allowed, provided they do not significantly impact on the activities as stated in the application, and they comply with the applicable terms and conditions. Other changes to the implementation require approval from the Swedish Research Council.

2.4 Scientific responsibility
If the activities include research, the applicant has scientific responsibility for the implementation of the research in respect of object and method. As scientifically responsible, the applicant is responsible for ensuring the research is implemented according to the application and research plan as stated in Section 2.3.

As scientifically responsible, the applicant shall also
• ensure that the research is implemented according to good research practice
• ensure that the permits and approvals required have been obtained before the research is started. These may include permits from the Swedish Medical Products Agency or approval from the Swedish Ethical Review Authority or an ethical committee on animal experiments.
• submit scientific reports according to the Swedish Research Council's instructions and
• publish the results of the research according to the Swedish Research Council's instructions and terms and conditions (see Section 3.1).

2.5 Organisational responsibility
The administrating organisation is responsible for ensuring there is a fit-for-purpose organisation for implementing the activities.

The responsibility includes
• in its capacity as employer, ensuring that the personnel involved, including the project leader, are able to use their working hours to the extent required to implement the activities according to the approved application which also includes publishing the results

• ensuring the personnel involved have access to premises, equipment and other resources required to implement the activities, and
• ensuring that the permits and approvals required have been obtained before the activities are started.

If the activities include research, the administrating organisation is also responsible for ensuring that
• the research is implemented according to good research practice
• the research does not have commercial ties that affect its objectivity, independence or openness, and
• a data management plan is drawn up before the research starts, and that the plan is maintained and complied with.

2.6 Reporting on implementation
The applicant is responsible for submitting reporting on the implementation of activities according to the Swedish Research Council's instructions.

2.7 Employment relationship
If the applicant is a physical person, they shall be employed by the administrating organisation stated in the decision to award funding or by another approved administrating organisation that, following an application to change, has been approved by the Swedish Research Council. The employment relationship shall exist at the start of the grant payment period and last throughout the payment period and any further availability period.

An exception from the requirement to be employed by the administrating organisation may be allowed, after approval by the Swedish Research Council, for applicants employed by a Swedish region but where activities are implemented at an other administrating organisation, or otherwise where the Swedish Research Council on application allows an exception.

2.8 Equipment
The administrating organisation shall be the owner of the equipment and other fixtures and fittings procured for the activities. The equipment shall be used for the activities for as long as they are conducted.

2.9 Changed preconditions for implementation
The administrating organisation and applicant shall inform the Swedish Research Council without delay if circumstances arise that entail the activities cannot be implemented within the availability period according to what follows from the application, grant decision, or terms and conditions. The same applies if equipment, for which purchase funding has been awarded, cannot be procured. In this case, the administrating organisation shall also report how the activities are affected by the equipment being impossible to procure.

2.10 Changing administrating organisations
If the activities can no longer be implemented at the administrating organisation due to changed circumstances, the Swedish Research Council may, on application from the administrating organisation and applicant, assess the issue of changing administrating organisations. The corresponding applies if the applicant is changing employers to another approved administrating organisation. An application to change administrating organisations shall be made in consultation with the administrating organisations involved.

2.11 Changing project leaders

If the activities can no longer be implemented due to changed circumstances for the project leader, the Swedish Research Council may on application approve a change of project leaders. The Swedish Research Council's decisions shall, if possible, be preceded by consultation with the project leaders.

2.12 Other funding
A precondition for the Swedish Research Council's decision is that the administrating organisation or applicant have not already received or will receive other funding for the same costs and purpose.

If other funding is awarded for the same costs and purpose, the administrating organisation and applicant must without delay notify the Swedish Research Council of this. The notice shall state what the overall funding for the purpose is, how the preconditions for the application the Swedish Research Council's decision was based on have been affected, and also to what extent other funding may impact on the implementation of the activities. The notice shall also describe any impact on the analysis, interpretation or reporting of the results, and also who will dispose of these.

The Swedish Research Council may change a decision to award funding on the basis of information about other funding.

3. Publication and dissemination of results and information

3.1 Publication of results
The applicant is responsible for ensuring the results of activities are published according to the Swedish Research Council's instructions. The obligation to publish results only applies to the extent the publication may be done according to legislation as applicable in Sweden.

The results of research shall be published in scientific journals and books with national and international reach, or be made available in another corresponding way. An agreement with a commercial actor or other stakeholder must not limit the opportunities to publish the results of research carried out with funding from the Swedish Research Council. Nor may such an agreement delay publication by more than two months. However, the delay may amount to at most four months if the purpose is to enable a patent application based, wholly or partly, on the research results referred to above.

Research results shall be published in accordance with the Swedish Research Council's guidelines for publication with open access.

The applicant is also responsible for ensuring research results of general interest are disseminated to recipients outside the research community.

3.2 Information about the Swedish Research Council's funding
When publishing or otherwise disseminating results, the applicant is responsible for ensuring it is stated that the activities were conducted with funding awarded by the Swedish Research Council. When publishing original scientific articles, the name "Swedish Research Council" and the registration number of the application to the Swedish Research Council shall be stated under the heading "Acknowledgements" or corresponding.

3.3 The Swedish Research Council's right to disseminate data
The Swedish Research Council may reproduce and disseminate whole or parts of reports from activities submitted to the Swedish Research Council, and also otherwise make available information about the activities.

4. Payment and use of the funding

4.1 Payment and availability period
The funding is paid out to the administrating organisation. The administrating organisation is responsible for receiving and administering the funding.
The decision to award funding states the period during which the funds will be paid out (the 'payment period'). Unless the decision states otherwise, the funding may be used for one additional year after the end of the payment period.

If special reasons exist, and following application, an extension of the period during which funding paid out is available may be allowed.
Such an application shall be submitted by the applicant and, as applicable, be approved by the administrating organisation via the Swedish Research Council's application system after the end of the payment period, but no later than 60 calendar days before the end of the availability period.

4.2 Use of the funding
Funding awarded shall be used to cover costs for implementing the activities according to the terms and conditions and mainly in the way stated in the application, however with such adjustments as may be required if the funding awarded is less than the amount applied for, or the grant period is shorter. For more major changes to the use of the funding, approval by the Swedish Research Council is required. A 'major change' refers to a change in the cost type of more than 25 per cent of the amount awarded, and entails a change that amounts to no less than 500 000 SEK, in relation to the entire grant period. Such as request shall be made by the administrating organisation and the applicant in conjunction with the need for the change arising.

The funding covers direct costs and indirect costs as a percentage of the direct costs, according to the cost basis decided on by the administrating organisation.

Funding awarded may only be used for annual depreciation costs for equipment during the period when the funding is available.

The funding awarded may not be used
• for scholarships
• for costs that are not directly related to implementing the activities, as described in the application
• to co-fund projects funded by grants from other research funding bodies, or
• for economic activities within the administrating organisation.

5. Financial reporting

5.1 Annual financial report
The administrating organisation shall submit an annual financial report to the Swedish Research Council. The financial report shall be submitted according to the Swedish Research Council's instructions.
The Swedish Research Council does not accept costs that are not directly related to implementing the activities, as described in the application.

5.2 Final financial report
The administrating organisation shall submit a final financial report no later than three months after the end of the availability period. The financial report shall be submitted according to the Swedish

Research Council's instructions. The Swedish Research Council may decide that the financial report shall be submitted at another time.
The Swedish Research Council does not accept costs that are not directly related to implementing the activities, as described in the application.

5.3 Final financial report if funding is discontinued or the activities are terminated early
If the Swedish Research Council decides that the funding shall be discontinued or if the activities are terminated early, the administrating organisation shall submit a final financial report to the Swedish Research Council within 30 days. The time is calculated from the day the activities were terminated early or the day the Swedish Research Council decided to discontinue the payment of funding. The Swedish Research Council may decide that the financial report shall be submitted at another time.

5.4 Final financial report after changing administrating organisations
If the Swedish Research Council has decided on a change of administration organisations, the retiring administrating organisation shall submit a final financial report to the Swedish Research Council within 30 days after the Swedish Research Council's decision.

5.5 Repayment of unused funding
Unused funding accounted for in the final financial report shall be repaid to the Swedish Research Council within 30 days after the final financial report was submitted via the Swedish Research Council's application system.

Unused funding corresponding to less than one half of a price base amount for the year the final report is submitted may be retained on condition that it can be used for purposes similar to that of the grant. If the unused funding exceeds one half of a price base amount, it must be repaid in its entirety.

6. Follow-up and audit

6.1 Providing information for follow-up, etc.
The administrating organisation and the applicant shall provide the information requested by the Swedish Research Council in conjunction with follow-up and evaluation of the activities, both during and after the payment period.

Accounts and reports relating to the activities funded by the Swedish Research Council shall be submitted according in the order stated in the decision to award funding, or when the Swedish Research Council so requests.

6.2 Audit
An auditor or corresponding appointed by the Swedish Research Council is entitled to scrutinise the book-keeping and reporting relating to the activities awarded funding by the Swedish Research Council. For this purpose, the administrating organisation shall give the person conducting the audit full insight, for example by supplying copies of all verifications relating to expenses and income attributable to the activities.

7. Actions if terms and conditions are not complied with

7.1 Demand to comply with terms and conditions and action plan
If the administrating organisation or applicant disregards or otherwise fails to comply with terms and conditions, and the failure cannot easily be corrected, the Swedish Research Council may require correction within a certain time. The Swedish Research Council may also require that the

administrating organisation or applicant submits an action plan describing when and how the terms and conditions will be complied with. The Swedish Research Council will evaluate whether the action plan can be approved, or whether the funding shall no longer be paid out.

7.3 Decision to discontinue payment of funding
The Swedish Research Council may decide to discontinue the payment of funding wholly or partly if
• there are no preconditions for implementing the activities according to the application, decision, or terms and conditions
• the funding has not been used according to the terms and conditions
• the applicant or the administrating organisation caused the funding to be awarded incorrectly or in too high an amount, through providing incorrect information or in some other way
• the funding was awarded incorrectly or in too high an amount for some other reason, and the administrating organisation or applicant should have realised this
• the applicant, or another person participating in the implementation of the activities, has been found guilty of scientific misconduct according to Swedish legislation on good research practice (SFS 2019:504), or in some other way has not complied with good research practice
• the applicant, in or in conjunction with the research, through actions or otherwise has shown themselves to be an unsuitable recipient of funding from the Swedish Research Council, or
• the terms and conditions have not been complied with in some other way, and the failure cannot easily be corrected.

Laerdal Foundation

1.

The following will be sent to the administrator of the Foundation within 12 months from date:
a.
a report of the progress/results of the project (e.g. an abstract, or a published article), and

b.
a specification of expenditures from the grant money, as well as total funding of the project.

2.

It is realized and agreed that the Foundation shall bear no responsibility for the project, whether legal, ethical or of any other nature.

It is further agreed that any involvement of patients/persons in the project shall be in accordance with the regulations of the Institutional Research Review Committee, or equivalent which is acceptable to the nation(s) concerned.

3.

In any publication about the project, the Laerdal Foundation will be referenced/.acknowledged.

4.

A final report within 3 years after receiving support.

5.

Should it, for whatever reason, not be possible to start the project for which financial support has been granted from the Foundation according to our application within 12 months from receipt of the grant, the grant will be returned to the Foundation.

SCHEDULE 3: FINANCIAL PLAN

This financial plan covers the setup and conduct of the Trial in the first 10 Study Sites.

Cost	Amount (SEK)
Project management and data collection	2 250 000
Ethics and regulatory submissions	250 000
Site monitoring	160 000
Study intervention and insurance	1 050 000
Total	3 710 000

SCHEDULE 4: PAYMENT PLAN

Invoice	Time period covered	Amount (SEK)
1 upon signing of this agreement	Jan 1 – December 31 2024	1 310 000
2 in Jan 2025	Jan 1 – Jun 30 2025	1 200 000
3 in Jul 2025	Jul 1 – Dec 31 2025	1 200 000