

Data Sharing Agreement

This Data Sharing Agreement (“**Agreement**”) is made as of 13 June 2024 (the “**Effective Date**”) by and between the Karolinska Institutet (org.nr 202100-2373), a medical university having an address at 171 77 Stockholm, Sweden (“**KI**”) and **George Institute for Global Health** (CIN - U74900TG2007NPL055085), a not-for-profit company registered under the Companies Act, 1956, having an address at 308, Third Floor, Elegance Tower, Plot No. 8, Jasola District Centre, New Delhi, India (“**GI-India**”).

Each of KI and GI-India may be referred to herein individually as a “**Party**” and collectively as the “**Parties**”.

The Parties are committed to the furtherance of science and public health and this Agreement establishes the terms and conditions under which the parties listed above can access and use data from the other parties related to the research study “Effects of Advanced Trauma Life Support® Training Compared to Standard Care on Adult Trauma Patient Outcomes: A Cluster Randomised Trial”. Parties listed above may be providers and/or recipients of data.

For the purposes of this Agreement, data shall mean the de-identified/anonymized clinical and/or health information pertaining to patients or participants recruited for the Study (including the information from case report forms and operational documents), and any analyses thereof (“**Data**”).

1. **Applicable Laws.** For the purposes of this Agreement, “**Applicable Laws**” include all applicable laws, rules and regulations of any central or state governmental or regulatory authority in India that apply to the conduct of Research or other activities contemplated hereunder, including where applicable (a) the Indian Council for Medical Research (“**ICMR**”) - National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017 (“**ICMR Ethical Guidelines**”); (b) Information Technology Act, 2000 and rules, by-laws, regulations and other notifications made or issued thereunder, as amended from time to time; (c) New Drugs and Clinical Trials Rules, 2019; (d) Data will be collected in a standardized case record form approved by institutional/project committees and stored consistent with the National laws, such as “**Digital Personal Data Protection Act 2023**”; and (e) any other personal or non-personal data protection, governance or regulatory framework or statute in force in India from time to time (including all the rules, by-laws, regulations and other notifications made or issued thereunder)
2. Parties will maintain all Data and any other study data in a reasonably secure manner employing privacy and security best-practices to minimize the chances of unauthorized use or access.
3. Parties will ensure that prior to any sharing of Data, individual-level study data is removed of any personally identifying information.

4. All data collected for this study will be used and analysed exclusively as per the objectives pertaining to the proposal submitted to the Health Ministry's Screening Committee.
5. Parties will adhere to the publication policy outlined in the Protocol version V1.1.0 2024-03-28. Authorships will be determined following guidelines developed by the International Committee of Medical Journal Editors (ICJME). Publications will be reviewed by all investigators and their institutions prior to release.

The duly authorized Party representatives have executed this Agreement as of the date first set forth above.

The Karolinska Institutet (KI)


By: 
Name: Martin Gerdin Wörnberg

Title: Principal investigator, Associate Professor

The Karolinska Institutet (KI)

By:
Name:
Title:

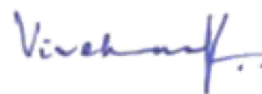
George Institute for Global Health (GI India)

By: 

Name: Amit Khanna

Title: Director – Finance and Operations

George Institute for Global Health (GI India)

By: 

Name: Vivekanand Jha

Title: Director – Executive Director

