



THE UNIVERSITY
of EDINBURGH



GLOBAL SURG 4 DATA CONTRIBUTOR AGREEMENT

Dear Collaborator,

Thank you for your interest in contributing Data to GlobalSurg 4 (“GECKO” or the “Project”).¹ This letter, including the Schedule hereto (collectively the “Agreement”), sets forth the terms by which your institution may provide Data to the University of Edinburgh (“Edinburgh”)² for use in GECKO.

GECKO aims to determine variation of laparoscopic gallbladder surgery worldwide. Recent multicentre collaborative studies have indicated that patient readmissions and post-operative complications place a significant burden on healthcare systems. Surgical societies are currently focusing on creating a culture of safety around this procedure. The Project will be an international collaborative study with contemporaneous data collection on the quality of cholecystectomies using measures covering infrastructure, care processes and outcomes. The primary aim of this study is to define the global variation in compliance with pre-, intra-, and post-operative audit standards.

By contributing Data to GECKO your institution (hereafter the “Contributor”) agrees to be bound by this Agreement, including the Terms and Conditions set forth at Schedule Part 1 hereto. Please make sure to read the Terms and Conditions below, and if you have any questions, please contact gecko@globalsurg.org.

¹ The Wellcome Trust funded Global Surgery Health Technology Evaluation and Validation Consortium” as set forth in greater detail in the Protocol.

² The University Court of the University Of Edinburgh, a charitable body registered in Scotland under registration number SC005336 incorporated under the Universities (Scotland) Acts and having its main administrative offices at Old College, South Bridge, Edinburgh EH8 9YL.

SCHEDULE PART 1

TERMS & CONDITIONS

For the purposes of this Agreement, the following terms shall have the following meanings:

Agreement	means this GlobalSurg 4 (GECKO) Data Contributor Agreement including all schedules hereto;
Applicable Law	means in respect of either Party, all laws, statutes, regulations, directions, guidelines and codes of conduct of any governmental or other regulatory body of competent jurisdiction which are applicable to the performance by that Party of its obligations or enjoyment of its rights under this Agreement, including the Data Protection Laws.
Contributor	the institution contributing Data to Edinburgh hereunder;
controller, data subject, data subject request, personal data, processor, process, processed and processing	shall have the meaning given to those terms in the applicable Data Protection Laws;
Data	means de-identified patient, hospital and outcome variables that the Contributor sends to Edinburgh for purposes of the GECKO Project as set forth in greater detail in the Protocol;
Data Protection Laws	means: (a) the UK GDPR, the Data Protection Act 2018, and the Privacy and Electronic Communications (EC Directive) Regulations 2003, all as amended by the Data Protection, Privacy and Electronic Communications (amendments etc) EU Exit Regulations 2019; (b) to the extent applicable, the GDPR; (c) any other directly applicable laws or regulations relating to data protection and privacy; and (d) applicable guidance and codes of practice issued by a data protection or privacy regulator; all as amended from time to time or replaced by successor legislation, regulation, guidance or codes of practice;
Derived Data	means data or data sets created or derived from the analysis or use of the Data during the course and scope of the Project as set forth in the Protocol. For avoidance of doubt, Derived Data does not include the Data itself.
Party	shall mean Edinburgh and the Collaborator (collectively Parties);
Protocol	means the approved Gecko Study Protocol dated 14 May 2023 as may be amended from time to time.
UK GDPR	means the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27th April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (GDPR) as it forms part of the law of England and Wales, Scotland and Northern Ireland by virtue of section 3 of the European Union (Withdrawal) Act 2018.

1. Edinburgh and the Contributor are separate controllers and each shall be solely responsible and liable for its own processing of the Data including (without limitation) the lawful basis for that processing and ensuring that the Data is processed in compliance with the Data Protection Laws.
2. The lawful bases for Edinburgh's processing of personal data for the Project shall include, without limitation, Article 6(1)(a) (consent); (e) (performance of a task in the public interest); Article 9(2)(a) (consent); and (j) (processing in the public interest, scientific or historical research or statistical purposes) of UK GDPR.
3. The Contributor shall retain ownership of the Data, provided that the Contributor grants Edinburgh the right to use the Data for the purposes of the Project and in accordance with this Agreement. Edinburgh will own any Derived Data created in the course of its use of the Data for the Project. For avoidance of doubt, Edinburgh shall not make any commercial use of the Data.

4. The Contributor shall provide the Data to Edinburgh via the secure Research Electronic Data Capture (REDCap) web application, as set forth in the Protocol. The Contributor shall ensure that all Data that it provides to Edinburgh is provided in de-identified form without the identification key or other means for Edinburgh to re-identify individuals from the Data.
5. The Contributor shall ensure that the Data has been collected in accordance with Applicable Law, and that all notices, consents, and/or regulatory and ethical approvals required by law have been given and are sufficient in scope to enable the Contributor to provide the Data to Edinburgh for use in the Project.
6. The Contributor shall promptly notify Edinburgh (and, in any event, within two working days) of any data subject request or correspondence from a data protection or privacy regulator that affects Edinburgh's use of the Data for the Project. Contributor and Edinburgh shall cooperate to enable the Contributor to reasonably respond to any such request. The Contributor shall be responsible for providing any follow-up notice or correspondence to a data subject required by the Data Protection Laws.
7. Edinburgh agrees that:
 - 7.1. it shall not attempt to re-identify any individual from the Data or contact any individual data subject;
 - 7.2. it shall use the Data solely for the purpose of carrying out the Project as set forth in the Protocol;
 - 7.3. it shall not make any copies of the Data except as may be necessary for the purpose of carrying out the Project;
 - 7.4. it shall keep the Data secure by implementing organisational and technological measures appropriate to the nature and sensitivity of the Data to prevent the unauthorised or accidental access, use or disclosure of the Data;
 - 7.5. it shall notify the Contributor as soon as reasonably practicable (and, in any event, within two working days) after becoming aware of any unauthorised or accidental access, use or disclosure of the Data, and to cooperate with any investigation made by the Contributor in connection with the unauthorised or accidental access, use or disclosure of the Data;
 - 7.6. it shall notify the Contributor within two working days of any data subject request or correspondence from a data protection or privacy regulator in relation to the Data and where required, shall provide the Contributor with all information that may be reasonably required to enable the Contributor to respond to such data subject request or correspondence from the regulator;
 - 7.7. it shall keep the Data confidential as long as such Data remains confidential in nature, other than for purposes of the Project. This obligation of confidentiality shall not apply where the Data and/or confidential information:
 - (a) has become public knowledge, other than through an unauthorised disclosure by Edinburgh;
 - (b) was already known to Edinburgh prior to disclosure by the Contributor or was independently developed by Edinburgh without use of or recourse to the Data;
 - (c) was disclosed to Edinburgh by a third party not under any obligation of confidence to the Contributor;
 - (d) is required to be disclosed by law or by requirement of a regulatory body or court order;and
 - 7.8. unless otherwise agreed by the Contributor, it shall permanently delete all copies of the Data from its hard drives and movable media and destroy all physical copies of the Data as soon as reasonably practicable on completion of the Project or on termination of this Agreement (if earlier).
8. Edinburgh shall not provide any third party access to the Data for any purpose other than the completion of the Project. Where a third party research collaborator requires access to the Data for purposes of the Project, such access will be granted solely through Edinburgh servers pursuant to a binding data access agreement between Edinburgh and the collaborator in compliance with the Data Protection Laws and the terms of this Agreement.
9. Publications made by the Project team arising from analysis of the Data will be made in accordance with normal academic practice and shall provide appropriate acknowledgement of the contributions of the Contributor.
10. It is agreed that neither Party shall be liable for any indirect or consequential damages incurred by the other under or in connection with this Agreement howsoever caused. Nothing in this Agreement excludes, restricts or otherwise limits a Party's liability for any death or personal injury arising from its negligence or for any loss suffered by the other Party as a result of its fraud. The Contributor agrees to hold Edinburgh and its staff and students harmless for any claims arising out of the Contributor's own actions or omissions pertaining to its collection and/or provision of the Data for purposes of the Project.
11. This Agreement shall be governed by Scots law and the Scottish courts shall have exclusive jurisdiction over any matter relating thereto.