# **ISARIC TERMS of SUBMISSION**

# **DATA SHARING AGREEMENT (PSEUDONYMISED DATASET)**

Between

The institution providing the Data as named in the signature section of this agreement (the “Partner Institution”)

and

**THE CHANCELLOR MASTERS AND SCHOLARS OF THE UNIVERSITY OF OXFORD**, whose administrative office is at University Offices, Wellington Square, Oxford, OX1 2JD, United Kingdom, which includes the research group ISARIC who will execute the activities described herein (“ISARIC/Oxford”)

hereinafter referred to as “the Parties” and each of them being “a Party”

# BACKGROUND

1. The Parties are conducting research on infectious diseases as described in more detail at Schedule 1 (the “Research”). ISARIC/Oxford wishes to access and use the data subject to the specified Data and Data Protection clauses in Schedule 2 (the “Data and Data Protection”) for the purpose of the Research.
2. The Partner Institution is willing to supply the Data to ISARIC/Oxford and ISARIC/Oxford is willing to receive, use and store the Data in accordance with the terms and conditions contained within this agreement (the “Agreement”).
3. The Partner Institution acknowledges that the Data shared forms part of the larger Project coordinated by ISARIC/Oxford and the intention is to combine Data from other involved Parties to undertake the Research.

# TERMS AND CONDITIONS

It is hereby agreed as follows:

## In this Agreement:

## the term “Data” includes the data submitted by the Partner Institution and Manipulated Data;

## the term “Manipulated Data” means any Data that:

## ISARIC/Oxford adapts or combines or aggregates (wholly or in part) with any other data or information (but does not include that other data or information); and which

## has not been manipulated by ISARIC/Oxford to such a degree that it can no longer be identified as originating from the Data nor used as a substitute for the Data;

1. the term “Research” includes the publication (if any) of the results of the Research by ISARIC/Oxford or institutions collaborating with ISARIC/Oxford in accordance with clause 10;
2. the terms “personal data”, “controller”, “processes”, “processing” and “processed” shall have the meanings given in the Data Protection Laws;
3. “Data Protection Laws” means the Data Protection Act 2018 as amended from time to time and any successor legislation in the UK, and (for so long as and to the extent that the law of the European Union has legal effect in the UK) the General Data Protection Regulation (EU) 2016/679 (“GDPR”) and any other directly applicable European Union regulation relating to data protection and privacy.

## In consideration of the obligations accepted by ISARIC/Oxford under this Agreement, the Partner Institution grants to ISARIC/Oxford for the term of this Agreement set out in clause 14 a non-exclusive, personal and non-transferable licence to use the Data for the Research. As applicable and in accordance with applicable laws and regulation that apply to the Data, the Partner Institution shall use reasonable endeavours to ensure that it does not share or provide access to any Data under this licence (a) in breach of any legal or contractual obligation or restriction that it is subject to or (b) contrary to the terms of any favourable ethical opinion that relates to the Data.

## ISARIC/Oxford undertakes to the Partner Institution:

## to use the Data solely for the Research;

1. to restrict access to the Data to ISARIC/Oxford, those staff and students comprising the ISARIC/Oxford research team, and the collaborating researchers executing Research as an ISARIC/Oxford researcher, and to ensure that those staff, students, and researchers are aware of and comply with the terms of this Agreement;

## to keep the Data confidential and not sub-license, transfer, disclose or otherwise make available the Data in whole or part to any third party except as permitted by this Agreement, without specific prior written consent from the Partner Institution;

1. to 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, including (without limitation) the measures set out in clause 4;
2. to notify the Partner Institution as soon as reasonably practicable after becoming aware of any unauthorised or accidental access, use or disclosure of the Data, and to co-operate with any investigation made by the Partner Institution in connection with the unauthorised or accidental access, use or disclosure of the Data;

## not attempt to re-identify any individual from the Data or communicate with any individual re-identified from the Data, nor to link or attempt to link the Data to other data or information except as described Schedule 1 or with specific prior written consent from the Partner Institution;

## to process the Data in accordance with all applicable laws and regulations;

1. to agree with the Partner Institution that where applicable ISARIC/Oxford shall delete all copies of the Data from its hard drives and movable media and destroy all physical copies of the Data upon Partner Institutions request to remove the processed Data from ISARIC/Oxford’s data platforms, except to the extent ISARIC/Oxford is required by law to store the Data. This obligation does not extend to automatically generated computer back-up or archival copies generated in the ordinary course of ISARIC/Oxford’s information systems procedures, provided that ISARIC/Oxford makes no further use of those copies.

## In particular (and without limiting the generality of the preceding wording) ISARIC/Oxford shall not make physical or electronic copies of the Data except to the extent defined in the Research and shall ensure that any copy of the Data stored on its data platform is properly protected with firewall and controlled access permissions. ISARIC/Oxford shall keep a record of where each copy of the Data is stored and shall provide the Partner Institution with a copy of this record on request.

## The Data is supplied by the Partner Institution in pseudonymised form without the pseudonymisation key or other means for ISARIC/Oxford to re-identify individuals from the Data. The Parties anticipate that the Data is likely to be personal data in respect of the Partner Institution’s processing but not likely to be personal data in respect of ISARIC/Oxford’s processing, but this is a question of fact determined by the nature of the Data, the arrangements between the Parties, and any other means available to ISARIC/Oxford (whether publicly available or otherwise) to re-identify individuals form the Data. In the event that the Data is or becomes personal data when held or processed by ISARIC/Oxford, the Parties agree that:

## The Partner Institution shall be considered as the Controller and ISARIC/Oxford shall be a Processor.

## 

## Except to the extent prohibited by law, ISARIC/Oxford assumes all direct liability for damages which may arise from its receipt, use, storage or disposal of the Data. The Partner Institution will not be liable to ISARIC/Oxford for any use made, storage or disposal of the Data, including any loss, claim or demand made by ISARIC/Oxford or made against ISARIC/Oxford by a third party, due to or arising from the use, storage or disposal of the Data by ISARIC/Oxford, except to the extent permitted by law when caused by the gross negligence or wilful misconduct of the Partner Institution.

## The Partner Institution provides the Data ‘as is’ and makes no representation and gives no warranty of any kind, either express or implied, including but not limited to warranties of accuracy or fitness for a particular purpose, or that the use of the Data will not infringe any patent, copyright, trademark or other proprietary rights. Research data is often contributed by third parties and cannot be guaranteed to be free from errors, omissions or inaccuracies, accordingly the Partner Institution will not be liable to ISARIC/Oxford for any loss, damage, claim or liability arising from any reliance placed on the Data by ISARIC/Oxford.

## Nothing in this Agreement limits or excludes either party’s liability for (a) death or personal injury resulting from negligence; or (b) any fraud or for any sort of other liability which, by law, cannot be limited or excluded.

## The liability of either Party for any breach of this Agreement, or arising in any other way out of the subject matter of this Agreement, will not extend to loss of business, or profit, or to any indirect or consequential damages or losses.

## The Data are provided and the Research is undertaken in pursuit of the primary charitable objectives of advancing health, knowledge, and education through research and teaching. Results of the Research shall belong to the Party that generates such results (except that the Partner Institution retains ownership of the Data to the extent incorporated or included within the results), and that ISARIC/Oxford may seek to publish the results of the Research with the Partner Institutions following normal academic publishing practise. For the avoidance of doubt, ISARIC/Oxford shall procure that in relation to any publication reporting on the results of the Research, ISARIC/Oxford acknowledges the Partner Institution as the source of the Data in the publication and acknowledges the funder that funded the collection and compilation of the Data, in the form specified by the Partner Institution or the funder itself. ISARIC/Oxford shall provide a copy of such publication to the Partner Institution thirty (30) days in advance of submission for publication, to allow the Partner Institution (as sponsor of the original study under which the Data were collected) an opportunity to comment on the publication. ISARIC/Oxford shall not publish any confidential or proprietary information belonging to the Partner Institution without its prior written consent, including the Data in whole or in part. Confidential and proprietary information shall be deemed to include information which was described as such at the point of disclosure and/or was marked as either “confidential” or “proprietary”. The confidentiality obligations in this clause shall not apply where the confidential or proprietary information:

1. has become public knowledge, other than through an unauthorised disclosure by ISARIC/Oxford;
2. was already known to ISARIC/Oxford, prior to disclosure by the Partner Institution;
3. was disclosed to ISARIC/Oxford by a third party, whom to ISARIC/Oxford’s knowledge, was not under any obligation of confidence to the Partner Institution;
4. was released from confidential status by written authorisation of the Partner Institution; or
5. is required to be disclosed by law or by requirement of a regulatory body or court order.

## Nothing in this Agreement grants ISARIC/Oxford any rights over the Data or under any patents, nor any right to use, or permit the use of, any products or processes containing the Data for any profit-making or commercial purposes (“Commercial Use”). Should ISARIC/Oxford wish to make Commercial Use of the Data and should the Partner Institution be willing and able to grant a licence for such purposes, the Parties shall negotiate in good faith to agree an appropriate licence or revenue sharing agreement on fair and reasonable terms.

## Nothing in this Agreement shall prevent or impede the Partner Institution from being able to use the Data for any purpose, including but not limited to sharing and licensing of the Data to third parties, whether public, private or third sector, for any purpose.

## The rights and obligations of the Parties are personal and may not be assigned at any time without the prior written consent of the other Party which consent shall not be unreasonably withheld; provided that it shall be a requirement in all cases of assignation that the assignee undertakes to perform all outstanding obligations of the assignor as though the assignee had been an original party hereto.

## This Agreement shall be effective from the date of execution by the Partner Institution and shall continue in force until terminated.

## Each Party may terminate this Agreement at any time without cause and without liability by giving notice to the other Party, such notice to take effect as specified therein.

## Any provision of this agreement that expressly or by implication is intended to come into or continue in force on or after termination of this Agreement, including ISARIC/Oxford’s obligations under sub-clause 3(f), shall remain in full force and effect.

## The Data are provided at no cost.

## The Parties shall procure that in carrying out their obligations under this Agreement, they will comply with all applicable laws, regulations and statutes, including those relating to modern slavery and anti-bribery and the Data Protection Laws. Non-compliance with this clause by a Party shall not be sufficient justification for another Party not to comply with its obligations under this Agreement.

## A person who is not a party to this Agreement shall not have any rights under or in connection with it.

## Notices

## The Partner Institution’s representative for the purpose of receiving notices shall until further notice be the name and email address provided on acceptance of this Agreement:

## Add contact details if different from those provided in the signature section below, otherwise leave blank.

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## ISARIC/Oxford’s representative for the purpose of receiving notices shall until further notice be:

## The Director of Research Services, University Offices, Wellington Square, OX1 2JD

## Email: research.services@admin.ox.ac.uk

## with a copy to:

## ISARIC Data, Big Data Institute, Old Road Campus, Roosevelt Drive, Oxford OX3 7FZ

Email: data@isaric.org

## This Agreement constitutes the entire agreement between the parties in respect of its subject matter and no statements or representations made by any Party have been relied upon by the other in entering into this Agreement.

## This Agreement shall be governed and construed in accordance with the laws of England and Wales and the Parties agree to the exclusive jurisdiction of the courts of England

## This Agreement may be executed in one (1) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. A signed copy of this Agreement delivered by e-mailed portable document format file or other means of electronic transmission shall be deemed to have the same legal effect as delivery of an original signed copy of this Agreement.

IN WITNESS WHEREOF this Agreement is executed as follows:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| for and on behalf of  Name of Partner Institution: | |  | | for and on behalf of  **THE CHANCELLOR MASTERS AND SCHOLARS OF THE UNIVERSITY OF OXFORD** | |
| Signed: |  |  | Signed: | |  |
| Signatory Name: |  |  | Name: | |  |
| Signatory Role: |  |  | Title: | |  |
| Email: |  |  |  | |  |
| Dated: |  |  | Dated: | |  |

Schedule 1

**The Research**

The **ISARIC Clinical Epidemiology Platform** is a suite of standardised, openly available tools to support collection, processing, and analysis of clinical data from individuals with emerging infectious disease. The platform is designed to accelerate research response to outbreaks and facilitate global collaboration through innovation.

The following research activities may be undertaken using data submitted to the platform, including data submitted by the Partner Institution:

1. Data hosting: On request, ISARIC may provide data management services to the Partner Institution, including hosting of a standard ISARIC REDCap project for data entry and export by Partner Institution sites.
2. Collaborative analyses: Researchers working at ISARIC/Oxford or at any ISARIC partner institution may request access to data hosted on the platform for the purpose of collaborative analysis. All requests for access will be circulated in the form of a Statistical Analysis Plan (SAP) to the Partner Institution that submitted the requested data. The Partner Institution is free to exclude their data from the proposed analysis by response to ISARIC within 30 days of SAP circulation.

Publications from analyses that progress will be circulated to the Partner Institution at least 30 days before publication submission for review and input. Use of data from the Partner Institution will be acknowledged in the group authorship of the publication via inclusion of the names of all Partner Institution staff communicated to ISARIC.

This data governance structure will apply to all other research listed below.

1a) Clinical epidemiology: Data will be analysed to characterise pathogen and host characteristics of disease. This includes, but is not limited to, patterns and predictors of clinical presentation, disease progression, clinical outcomes, treatments, and patient management.

1b) Data visualisation: Data will be analysed and shared as aggregate graphs, tables and charts to support the clinical characterisation of illness. Aggregated outputs (not including patient-level data) may be shared on publicly available dashboards.

1c) Minting of data DOI: ISARIC may assign a digital object identifier (DOI) to the submitted data. The DOI will link the data to information about the data (metadata, e.g., contributing staff, institution, collection dates) supplied by the Partner Institution.

1d) Data inventory: To communicate the contents of the ISARIC platform, a data inventory detailing the volumes and types of data hosted will be made publicly available in the form of a dashboard, that will be the way for other ISARIC partner institution to request data.

1e) Development of new analytical methodologies, coding techniques, and tools: Data will be analysed to further the development of adaptable and reusable analytical tools and methodologies within the ISARIC Clinical Epidemiology Platform. Key areas include, but are not limited to, determining the most effective machine learning and statistical models for predictive accuracy and interpretability, standardizing data pre-processing for cross-disease consistency, understanding and mitigating biases to better inform data collection, and defining validation criteria.

1e) Synthetic data: Data will be modelled to create synthetic datasets that mimic the statistical characteristics of the original data and enhance data privacy guarantees as they do not include real patient records from the original data. When patient data are scarce, synthetic data can be generated in large volumes to facilitate prediction modelling and prepare analytic responses. Synthetic data will be used for training, teaching, demonstrations, and presentations, and it will meet all requirements to be openly shared.

Schedule 2

**The Data and Data Protection**

Definitions

**Data Protection Legislation** means any law, statute, declaration, decree, directive, legislative enactment, order, ordinance, regulation, rule or other binding restriction (as amended, consolidated or re-enacted from time to time) which relates to the protection of individuals with regards to the processing of Personal Data to which a Party is subject, including the Data Protection Act 2018 and retained EU law version of the General Data Protection Regulation ((EU) 2016/679) (“**GDPR**”) and any successor legislation to the Data Protection Act 2018 and the GDPR.

**Controller, data controller, processor, data processor, data subject, processing** and **appropriate technical and organisational measures** have the meanings set out in the Data Protection Legislation in force at the time.

**Permitted Region** has the meaning given in clause 1.3.13

**Personal Data** means any personal data (as defined in the Data Protection Legislation) processed by either Party in connection with this Agreement.

1. DATA PROTECTION
   1. Both Parties will comply with all applicable requirements of the Data Protection Legislation. This Clause (Data Protection) is in addition to, and does not relieve, remove or replace, a Party's obligations under the Data Protection Legislation.
   2. The Parties acknowledge that for the purposes of the Data Protection Legislation, the Partner Institution is the controller and ISARIC/Oxford is the processor. Schedule 3 sets out the scope, nature and purposes of processing by ISARIC/Oxford, the duration of the processing and the types of Personal Data and categories of data subject.
   3. To the extent that ISARIC/Oxford processes any Personal Data as a processor for and on behalf of the Partner Institution (as the controller) it shall:
      1. only process Personal Data for and on behalf of the Partner Institution for the purposes of performing its obligations under this Agreement and only in accordance with the Partner Institution's written instructions from time to time, unless ISARIC/Oxford is required by the laws of the UK applicable to the Supplier (“Applicable Data Processing Law”) to process Personal Data. In such a case, ISARIC/Oxford shall inform the Partner Institution of that legal requirement before processing, unless the law prohibits such information on important grounds of public interest;
      2. inform the Partner Institution immediately if it considers any of the Partner Institution's instructions infringes Data Protection Legislation;
      3. ensure that it has in place appropriate technical and organisational measures to ensure a level of security appropriate to the risk and to protect against unauthorised or unlawful processing of Personal Data and against accidental loss or destruction of, or damage to, Personal Data, appropriate to the harm that might result from the unauthorised or unlawful processing or accidental loss, destruction or damage and the nature of the data to be protected, having regard to the state of technological development and the cost of implementing any measures (those measures may include, where appropriate, pseudonymising and encrypting Personal Data, ensuring confidentiality, integrity, availability and resilience of its systems and services, ensuring that availability of and access to Personal Data can be restored in a timely manner after an incident, and regularly assessing and evaluating the effectiveness of the technical and organisational measures adopted by it);
      4. ensure the reliability of any of its personnel who have access to the Personal Data and ensure that such personnel have committed themselves to confidentiality or are under an appropriate statutory obligation of confidentiality;
      5. taking into account the nature of the processing, at the Partner Institution’s request, assist the Partner Institution to comply with the obligations imposed on the Partner Institution by the Data Protection Legislation, and in the relevant timescales, in relation to: (i) security, breach notifications, data protection impact assessments, and consultations with supervisory authorities or regulators; and (ii) responding to any requests from data subjects.
      6. notify the Partner Institution promptly following its receipt of any request from a data subject to exercise their rights under the Data Protection Legislation or any correspondence from a supervisory authority or regulator and shall:
         1. not disclose any Personal Data without first consulting with and obtaining the University's prior written consent; and
         2. provide the Partner Institution with all reasonable co-operation and assistance required by the Partner Institution in relation to any such request or correspondence;
      7. notify the Partner Institution without undue delay [and in any event within twenty-four (24) hours)] upon becoming aware of any breach of the Data Protection Legislation in relation to the Personal Data and provide assistance to the Partner Institution as is necessary upon reasonable request to facilitate the handling of any data security breach relating to the Personal Data in an expeditious and compliant manner;
      8. keep a record of any processing of the Personal Data it carries out on behalf of the Partner Institution and hold the Personal Data in such a manner that it is capable of being distinguished from other data or information processed by Partner Institution;
      9. promptly comply with any request from the Partner Institution to amend, transfer or delete any Personal Data;
      10. at the written direction of the Partner Institution, delete or return Personal Data and copies thereof to the Partner Institution on termination of the Agreement unless required by Applicable Data Processing Law to store the Personal Data;
      11. at the Partner Institution’s reasonable request: (i) make available to the Partner Institution evidence to demonstrate the Supplier’s compliance with the requirements of this Clause (Data Protection); and (ii) allow for and contribute to audits, including inspections, conducted by or on behalf of the Partner Institution, on reasonable notice and subject to appropriate confidentiality obligations;
      12. not engage a third party processor of Personal Data under this Agreement (a sub-processor) unless they are included in the List of Sub-Processors in Schedule 3 or the Partner Institution in its absolute discretion otherwise gives its specific written authorisation; and where such authorisation is given, the Supplier:
          1. shall put in place a written agreement that imposes data protection obligations that are the same to those set out in this Agreement;
          2. acknowledges that the Supplier remains fully liable to the Partner Institution for the performance of any sub-contracted processing obligations,
      13. not transfer any Personal Data outside of the UK or the European Economic Area (the “**Permitted Region**”) or to an international organisation[[1]](#footnote-1) except:
          1. with the prior written consent of the Partner Institution and in accordance with any written instructions and terms the Partner Institution may impose on such transfer to ensure that transfers of Personal Data outside of the Permitted Region have adequate protections in place as set out in the Data Protection Legislation; or
          2. if required by Applicable Data Processing Law, in which case the Supplier shall inform the Partner Institution of that legal requirement before transferring, unless the law prohibits such information on important grounds of public interest.
   4. By entering into a Data Sharing Agreement with ISARIC/Oxford the Partner Institution understands how the Data will be used and confirms consent that the Data may be shared outside of the EEA. The Partner Institution shall give written notice to ISARIC/Oxford if it wishes to request removal of that Personal Data.
   5. Notwithstanding anything in the Agreement to the contrary, this Clause (Data Protection) shall continue in full force and effect for so long as the Supplier processes any Personal Data.

# Schedule 3

**Data Protection Particulars**

|  |  |
| --- | --- |
| **The subject matter and duration of the Processing** | Infectious disease characterisation, transmission, and treatment.  The current ISARIC3 project is active until May 2029. Data will be processed up to and after this date, until the point of termination of this Agreement by either Party. |
| **The nature and purpose of the Processing** | Data will be hosted, curated, aggregated with related datasets from other ISARIC Partner Institutions, stored, and made available for collaborative analyses to undertake the Research as described in Schedule 1. The purpose of this research is to characterise the transmission, treatment, and host/pathogen features of infectious diseases and to innovate methods for data processing and analysis to advance health research. |
| **The type of Personal Data being Processed** | Demographic and clinical data including age, medical history, health care admissions, vital signs, reported signs and symptoms, treatments, clinical findings, outcomes, and laboratory results. |
| **The categories of Data Subjects** | Individuals or their contacts with confirmed or suspect infectious diseases |

The controller has authorised the use of the Data by ISARIC Partner sub-processors. A list of current sub-processors is available here:

[**https://github.com/ISARICResearch/CCP/blob/4c67a9fd535b39a3f810ff92bf40a31ce09c2592/Analyses/Partner-Analyses-Metadata.xlsx**](https://github.com/ISARICResearch/CCP/blob/4c67a9fd535b39a3f810ff92bf40a31ce09c2592/Analyses/Partner-Analyses-Metadata.xlsx)

The Partner Institution will be informed of all new sub-processors in advance of data access as outlined in Schedule 1.

The Technical and Organisational Measures in place to protect data on the ISARIC platform are available here: [**https://github.com/ISARICResearch/CCP/blob/b6b5418464793a643e4b51deb2de08c932bbda01/Data-Governance/Technical-Organisational-Measures.docx**](https://github.com/ISARICResearch/CCP/blob/b6b5418464793a643e4b51deb2de08c932bbda01/Data-Governance/Technical-Organisational-Measures.docx)

**Summary Information for the transfer of Personal Data:**

|  |  |
| --- | --- |
| Partner Institution | As detailed in the signature section, or clause 20. |
| Partner Institution Name and contact email/details | As detailed in the signature section, or clause 20. |
| ISARIC Reference | Clinical Characterisation Protocol |
| Project title or Dataset | Clinical Epidemiology Platform |
| Consents given for Data collection and use given? | Consent of adult patients and consent of parent/guardian of participants under 18 years, or waiver of consent from responsible authorities. |
| Description of Data processing | As described in Schedule 1, processing and use of the Data |
| Term of use of Data | Date of execution by the Partner Institution until termination by either Party |
| Use of Processed Data for ISARIC projects by Data Users | <https://github.com/ISARICResearch/CCP/blob/4c67a9fd535b39a3f810ff92bf40a31ce09c2592/Analyses/Partner-Analyses-Metadata.xlsx> |
| Contact details and email for withdrawal of Data | ISARIC Data, Big Data Institute, Old Road Campus, Roosevelt Drive, Oxford OX3 7FZ  Email: data@isaric.org |

1. Defined as an organisation and its subordinate bodies governed by public international law, or any other body which is set up by, or on the basis of, an agreement between two or more countries (GDPR Article 4(26)) [↑](#footnote-ref-1)