

ISARIC DATA PLATFORM TERMS OF DATA SUBMISSION

BACKGROUND:

- (A) The International Severe Acute Respiratory and Emerging Infection Consortium Data Platform (ISARIC DP) is a collaborative repository that standardises, secures, and makes available for research, global data on infectious diseases of public health importance. The platform is hosted by the Infectious Diseases Data Observatory (IDDO).
- (B) The International Severe Acute Respiratory and Emerging Infections Consortium (ISARIC) and the Infectious Diseases Data Observatory (IDDO) are based at the University of Oxford. The University of Oxford is responsible for ISARIC's and IDDO's obligations set out in this Agreement. For the purposes of this Agreement ISARIC and IDDO mean "University of Oxford" to the exclusion of any other legal person.
- (C) The Data Contributor wishes to submit the Data to the ISARIC DP for the purpose of Curation and secure storage. These Terms include the option to additionally make the data available to third parties for research analysis via application to the Data Access Committee. The Data Contributor can indicate if they accept this additional option in the signature section.

1. DEFINITIONS

In this Agreement:

"Agreement" the current agreement, including appendix and any amendments;

"Applicable Regulations" means all laws, regulations, regulatory requirements and authorisations, decisions and guidance of regulatory authorities or other requirements applicable in the context of this Agreement in any jurisdiction, including those jurisdictions in which the Raw Data was collected or from which the Raw Data otherwise originate;

"Confidential Information" means any and all information disclosed by or on behalf of Data Contributor at any time that would be regarded as confidential by a reasonable person or information which is identified as being confidential or otherwise designated to show expressly that it is imparted in confidence;

"Curated Data" means the dataset hosted by ISARIC/IDDO following completion of Curation;

"Curation" or "Curate" means the process by which ISARIC/IDDO verifies, cleans, standardises and maps the data to a harmonised format and produces high-level, aggregated reports of case numbers, clinical features and outcomes;

"Data" means the Raw Data and Curated Data;

"Data Access Committee" means the independent committee appointed to approve third party access to Curated Data

"Data Contributor" or "Contributor" means the legal body responsible for the Raw Data contributed to the ISARIC Data Platform;

"Intellectual Property Rights" or "IPRs" means any and all patents, copyright, registered designs, design rights, trade marks, database rights, regulatory rights in data exclusivity and market exclusivity (including, without limitation, under U.S. laws, Directive 2001/83/EC and any national implementing legislation), know how and any other intellectual property rights anywhere in the

world in each case whether registered or unregistered, including any and all applications for such rights and the right to make such applications and all similar or equivalent rights or forms of protection which subsist or will subsist now or in the future in any part of the world;

“**Parties**” means the parties to this Agreement, including:

- (a) The Chancellor Masters and Scholars of the University of Oxford on behalf of ISARIC/IDDO, and;
- (b) The entity or institution on whose behalf Data are submitted to the ISARIC DP under this Agreement (the “Data Contributor” or “Contributor”).

“**Pseudonymisation**” means the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person;

“**Raw Data**” means any data submitted by or on behalf of the Data Contributor to the ISARIC DP;

“**ISARIC Data Platform**” or “**ISARIC DP**” means the platform developed and maintained by ISARIC, and hosted by IDDO, on which data concerning infectious diseases, contributed by a variety of data contributors, are collated and curated;

“**Third Party**” means any entity or person other than the Parties.

Definitions of the terms of the article 4 of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 which is applicable from 25 May 2018 (hereinafter “the General Data Protection Regulation”) shall apply to this Agreement.

2. DATA TRANSFER

- 2.1 The Parties shall undertake to comply with the applicable regulations on personal data processing and, in particular, with the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191 and implementing regulations (HIPAA) as applicable to the Data Contributor and the General Data Protection Regulation as applicable to ISARIC and any applicable related national legislation
- 2.2 Data Contributor hereby grants ISARIC/IDDO a limited, non-exclusive licence to use the Data for the purposes of (i) Curating and storing the Raw Data, OR (ii) Curating and storing the Raw Data and, sharing the Curated Data with third parties in accordance with clause 5.3. For the avoidance of doubt, approval of either option is recorded by the Data Contributor in the signature section below.
- 2.3 Data Contributor shall transfer the Raw Data to the ISARIC DP following execution of this Agreement.
- 2.4 ISARIC/IDDO acknowledges that it shall have no rights in or to the Data other than the right to use it in accordance with the express terms of this Agreement.
- 2.5 Nothing in this Agreement shall prevent the Data Contributor from being able to use the Data for any purpose, including but not limited to publication of the Data or distribution of the Data to Third Parties for research purposes.

3. CONTRIBUTOR OBLIGATIONS

- 3.1 The Data Contributor represents to ISARIC that:
 - 3.1.1 it has obtained all necessary licences, permits and/or consents or waivers thereof

- necessary for the storage, curation and use of the Data as permitted by this Agreement;
 - 3.1.2 the submission falls under pre-existing regulatory or ethics approvals or it has obtained any regulatory and/or ethics committee approvals required to submit the data to the ISARIC DP;
 - 3.1.3 the Data were collected in compliance with all Applicable Regulations that apply to the Data Contributor; and
 - 3.1.4 it has the right to enter into this Agreement.
- 3.2 The Parties acknowledge and agree that the intention is that the Data Contributor shall use all reasonable efforts not to transfer, disclose or otherwise make available any data that directly identifies a natural person to ISARIC.

4. PROCESSOR OBLIGATIONS

- 4.1 The Parties acknowledge and agree that, in the event that the Raw Data submitted to the ISARIC DP contains any personal data, ISARIC/IDDO shall process such personal data as a Data Processor for the sole purpose of Pseudonymizing the data and only in respect of Pseudonymising such personal data.
- 4.2 ISARIC/IDDO shall:
- 4.2.1 process the personal data only in accordance with the written instructions of the Contributor as Data Controller unless required to do so by law and subject to notifying the Contributor (save where by law it is prohibited from so notifying the Contributor);
 - 4.2.2 take reasonable steps to ensure the reliability of its employees, staff, officers and agents who may have access to, or be involved in, the processing of the personal data;
 - 4.2.3 ensure that the ISARIC/IDDO personnel who have access to and/or process the personal data are obliged to keep it confidential or are under an appropriate statutory obligation of confidentiality and the said personnel receive the appropriate personal data protection training;
 - 4.2.4 not permit Third Parties to process the personal data without obtaining Contributor's prior written consent;
 - 4.2.5 ensure that it has in place appropriate technical and organisational measures to protect against unauthorised or unlawful processing of personal data and against loss or destruction of, or damage to, personal data, appropriate to the harm that might result from unauthorised or unlawful processing or accidental loss, destruction or damage and the nature of the personal data to be protected, having regard to the state of technological development and the cost of implementing any measures;
 - 4.2.6 assist the Data Contributor, by having appropriate technical and organisational measures, in responding to any request from a data subject for exercising the data subject's rights;).
 - 4.2.7 assist the Contributor in its compliance with data protection legislation by:
 - (a) keeping the personal data secure;
 - (b) notifying the Contributor promptly and in any event within 24 hours of any personal data breaches so the Contributor can notify the supervisory authorities and advise data subjects;

- (c) conducting data protection impact assessments; and
 - (d) supporting the Contributor's interaction with supervisory authorities or regulators where the data protection risk assessment indicates that there is a high risk to the processing;
- 4.2.8 at the written direction of the Contributor, delete or return personal data and copies thereof to the Contributor on termination or expiry of this Agreement unless it is required to store the personal data by law.
- 4.2.9 maintain complete and accurate records and information to demonstrate its compliance with this Agreement and shall allow Contributor at reasonable times and from time to time to audit and review the compliance with this clause 4.2;
- 4.2.10 not transfer the personal data without first obtaining written consent from the Contributor or the Data Access Committee (if delegated by the Data Contributor to provide such consent) and, notwithstanding this provision of consent, not transfer the personal data except in accordance with data protection legislation, e.g. by entering into the European Commission's standard contractual clauses for the transfer of personal data to third countries adopted pursuant to Decision 2004/915/EC;
- 4.2.11 agree to any reasonable amendment to this clause 4.2 necessary to bring this clause 4.2 and ISARIC's obligations in respect of the processing of personal data into line with Applicable Regulations, as amended from time to time;
- 4.2.12 keep a record of any processing of the personal data it carries out; and
- 4.2.13 at the Data Contributor's reasonable request make available to the Data Contributor evidence to demonstrate ISARIC/IDDO's compliance with the requirements of this clause 4.2.

5. DATA CURATION AND PROCESSING TO BE CARRIED OUT BY THE PROCESSOR

- 5.1 ISARIC/IDDO is authorised, following submission of the Raw Data to the ISARIC DP to process the Raw Data in accordance with clause 4.2 prior to Curation. Without prejudice to Clause 3.2, ISARIC/IDDO shall permanently and irrevocably Pseudonymize any personal data contained within the Raw Data as part of the data curation process.
- 5.2 During the curation process, ISARIC/IDDO may contact the Data Contributor for clarification of Raw Data contents.
- 5.3 If approved by the Data Contributor as indicated in the signature section below and subject to clauses 4.2.10, 5.4 and 5.5 ISARIC/IDDO may make a description of the volumes and types of data (called metadata) publicly available, and share the Curated Data with third parties for research purposes ("Proposed Research") following written approval from the Data Access Committee.
- 5.4 Following approval for the sharing of Curated Data for the Proposed Research by the Data Access Committee, but prior to any such sharing, ISARIC/IDDO will invite the Data Contributor to participate with the Proposed Research in collaboration with the third party. The Data Contributor shall have the right but not the obligation to participate in the Proposed Research. For the avoidance of doubt, ISARIC/IDDO shall be entitled to share the Curated Data with the third party for the Proposed Research even if the Data Contributor declines to participate in the Proposed Research.
- 5.5 Sharing of the Curated Data will be under the terms of a separate data transfer agreement between

ISARIC and the third party.

6 PERMITTED USE OF THE DATA

6.1 ISARIC/IDDO shall not:

- 6.1.1 use, attempt to use or permit use of the Data to re-identify or contact any individual (living or deceased) or community associated with the Data; or
- 6.1.2 link, attempt to link or permit a Third Party to link the Data with any other data in a manner that may enable re-identification of individuals (living or deceased) or communities associated with the data; or
- 6.1.3 during the term of this Agreement or at any time thereafter disclose Confidential Information or the Data to any persons, except to its officers and employees who are under appropriate obligations of confidentiality and who need to access the Confidential Information and/or Data for the purposes described in this Agreement;

6.2 ISARIC shall:

- 6.2.1 ensure the Data is used in compliance with all Applicable Regulations at all times;
- 6.2.2 observe the highest standards of ethics and integrity in the course of use of the Data in order to promote respect for human rights, human dignity and privacy; and
- 6.2.3 comply with any reasonable instructions or restrictions with respect to use of the Data that Contributor may notify to ISARIC from time to time.

6.3 Notwithstanding Clause 6.1.3, ISARIC may disclose Confidential Information and/or the Data to the minimum extent required by an order of any court of competent jurisdiction or any regulatory, judicial, governmental or similar body of competent jurisdiction provided that prior to any such disclosure, ISARIC shall to the extent permitted by law use all reasonable endeavours to give Data Contributor as much notice of this disclosure as possible. Where notice is given, ISARIC shall take into account the reasonable requests of Data Contributor in relation to the content of the disclosure.

6.4 The provisions of Clause 6.1.3 shall not apply to Confidential Information which ISARIC can demonstrate by reasonable written evidence was, prior to its receipt by ISARIC, in its possession and at its free disposal, or subsequently disclosed to ISARIC by a third party without any obligations of confidence, or is or becomes available to the public through no act or default of ISARIC, or is independently developed, discovered or acquired by ISARIC without reference to any Confidential Information.

7 SECURITY

7.1 ISARIC/IDDO shall:

- 7.1.1 implement appropriate technical and organisational security measures having regard to the state of the art to protect the Data from unauthorised access and/or disclosure. In particular ISARIC/IDDO shall store the Data only on encrypted, access-limited, password-protected computers and/or servers. Any duplication of the Curated Data must be fully documented such that all versions can be deleted on request or on termination of this Agreement; and

- 7.1.2 notify Contributor immediately upon becoming aware of any unauthorised use or disclosure of, or access to, the Data and ISARIC/IDDO shall promptly take such action to remediate the same (which may include implementation of security measures to prevent the incident from recurring).

8 INTELLECTUAL PROPERTY

- 8.1 The Data shall remain the exclusive property of the Contributor and nothing in this Agreement transfers, or is intended to transfer, title to the Data or any IPRs relating thereto to ISARIC or any Third Party.
- 8.2 To the extent that any IPRs in the Curated Data do not vest automatically in Contributor, ISARIC hereby assigns (by way of present and future assignment) with full title guarantee all IPRs in the Curated Data to Data Contributor and shall procure that each employee waives such rights (including moral rights) as are not capable of being assigned.

9 LIMITATIONS AND EXCLUSIONS

- 9.1 Nothing in this Agreement excludes or limits the liability of either Party:
- 9.1.1 for death or personal injury caused by that Party's negligence; or
 - 9.1.2 for fraud or fraudulent misrepresentation; or
 - 9.1.3 to the extent that such liability cannot be limited or excluded by law.
- 9.2 Subject to Clause 9.1, in no event will the Contributor be liable for any use of the Data by ISARIC, whether in contract, tort (including negligence or breach of statutory duty) or otherwise howsoever arising.
- 9.3 ISARIC acknowledges that the Data is provided "as is" and Contributor hereby excludes all terms, conditions and warranties which, by virtue of statute, common law or otherwise, may, in the absence of this Clause, be implied into this Agreement with respect to the Data to the fullest extent possible.
- 9.4 Insofar as any liability may not be limited or excluded by law, the total liability of Contributor and ISARIC whether in contract, delict or otherwise, arising from or otherwise in connection with this Agreement shall not exceed one thousand pounds sterling (£1,000) in aggregate.
- 9.5 ISARIC warrants and undertakes that it has in effect, and will maintain in effect during the term of this Agreement and for a period of five (5) years thereafter, valid and enforceable insurance policies with reputable insurers appropriate to the nature of ISARIC's obligations under this Agreement or as may be required by applicable law from time to time.

10 DURATION AND TERMINATION

- 10.1 This Agreement shall commence on the date on which it is executed by the Data Contributor and shall continue in force until terminated in accordance with this Clause 10.
- 10.2 Each Party may give notice to terminate this Agreement at any time without cause and without liability by giving notice in writing to the other Party, such notice to take effect as specified therein.
- 10.3 If a decision is made to close the ISARIC DP, this Agreement shall automatically terminate.
- 10.4 Upon termination of this Agreement, all licences of the Data granted pursuant to this Agreement will automatically terminate and ISARIC shall (unless explicitly approved otherwise by the Data

Contributor in writing) securely destroy the Data and all Confidential Information in its (or their) possession or control and shall certify in writing to Contributor that it has (and they have) done so. Compliance with this Clause shall not require ISARIC to procure the withdrawal of any publicly available Publications as at the date of termination.

10.5 The termination or expiry of this Agreement shall not prejudice or affect any accrued rights or liabilities of any of the Parties.

10.6 Upon termination of this Agreement for any reason the provisions of Clauses 1 (*Definitions*), 2.4 to 2.5 (inclusive) (*Data Transfer*), 5.1 (*Data Curation*), 6.1 to 6.4 (inclusive) (*Permitted Use of Data*), 7 (*Security*), 8 (*Intellectual Property*), 9 (*Limitations and Exclusions*), 10 (*Duration and Termination*), 11 (*Third Party Rights*), 12 (*General*), 13 (*Notices*), 14 (*Interpretation*), 15 (*Disputes*) and 16 (*Governing Law*) shall remain in force.

11 THIRD PARTY RIGHTS

11.1 This Agreement does not create any right enforceable by any person who is not a party to it.

12 GENERAL

12.1 This Agreement may only be amended in writing signed by duly authorised representatives of ISARIC and Contributor.

12.2 ISARIC shall not assign, mortgage, charge or otherwise transfer or deal with any rights or obligations under this Agreement without the prior written consent of Contributor not to be unreasonably withheld, conditioned or delayed.

12.3 No failure or delay on the part of either Party to exercise any right or remedy under this Agreement shall be construed or operate as a waiver thereof, nor shall any single or partial exercise of any right or remedy preclude the further exercise of such or any other right or remedy.

12.4 Neither Party shall act or describe itself as the agent of the other, nor shall it make or represent that it has authority to make any commitments on the other's behalf.

12.5 Each Party shall at all times comply with all applicable laws, statutes, regulations and codes relating to anti-bribery and corruption and shall have and maintain appropriate policies and procedures to ensure compliance with such requirements (which it shall enforce where appropriate). Each Party shall immediately notify the other Party of any demand for any undue financial or other advantage of any kind received by it in connection with the subject matter of this Agreement.

12.6 This Agreement sets out the entire agreement between the Parties relating to its subject matter and supersedes all prior oral or written agreements (including Prior Agreements), arrangements or understandings between them relating to such subject matter. The Parties acknowledge that they are not relying on any representation, agreement, term or condition which is not set out in this Agreement.

13 NOTICES

13.1 All notices to be given and other documentation to be sent under the terms of this Agreement may be delivered personally or via email to the following:

13.1.1 in the case of ISARIC: NCoV@ISARIC.org

13.1.2 in the case of Contributor: the email address provided by the Contributor on acceptance

of this Agreement

- 13.2 Notices sent as above shall be deemed to have been received: if delivered personally, to such other address as may be notified to the other party in writing; or if sent by email, on the date the confirmation copy was deemed to have been received.

14 INTERPRETATION

In this Agreement:

- 14.1.1 references to the singular include the plural and vice versa;
- 14.1.2 where the word “including” is used it shall be understood as meaning “including without limitation”; and
- 14.1.3 any reference to any English law term for any action, remedy, method or judicial proceeding, legal document, legal status, court, official or any legal concept or thing shall in respect of any jurisdiction other than England be deemed to include what most nearly approximates in that jurisdiction to the English law term.

15 DISPUTES

- 15.1 In the event that any dispute arises out of or in connection with this Agreement (“**Dispute**”), the Parties shall attempt to resolve such Dispute in the first instance informally through discussion between suitably qualified individuals nominated by each Party and notified to the other in writing for this purpose from time to time. If within thirty (30) business days of the Dispute having been referred to such individuals no agreement has been reached, the dispute resolution procedure shall be deemed to have been exhausted and each Party shall be free to bring proceedings in accordance with Clause 10.
- 15.2 Notwithstanding anything to the contrary in this Agreement, each Party shall be entitled at any time to seek injunctive or other urgent relief in any court in any jurisdiction in connection with this Agreement.

16 GOVERNING LAW

- 16.1 The validity, construction and performance of this Agreement, and any contractual and non-contractual claims arising hereunder, shall be governed by English law and shall be subject to the exclusive jurisdiction of the English courts to which the Parties hereby submit.

EXECUTED

For and on behalf of

[Data Contributor: *Complete- Contributor Organisation*]

Signature

Name

Title

Email

Date

Data Contributor to initial below to record which is the approved option with respect to licensing of Data under clause 2.2

(i) Curating and storing the Raw Data_____

OR

(ii) Curating and storing the Raw Data and, sharing the Curated Data with third parties in accordance with clause 5.3. _____

For and on behalf of

Chancellor, Masters and Scholars of the University of Oxford

Denis Murphy

Signature

Denis Murphy

Name

Research Contracts Manager

Title

09 July 2020

Date