

# IDDO Data Platform Terms of Data Submission

## Background:

- (A) The Infectious Diseases Data Observatory (IDDO) has developed a collaborative data repository that standardises, secures, and makes available for research, global data on emerging and poverty related diseases of public health importance. The Platform is delivered in collaboration with key partners.
- (B) IDDO is based at the University of Oxford where the Platform is hosted. The University of Oxford is responsible for IDDO's obligations set out in this Agreement. For the purposes of this Agreement IDDO means "University of Oxford" to the exclusion of any other legal person.
- (C) The Data Contributor wishes to submit Raw Data to the Platform for the purposes of (i) Curation, (ii) Collaborative Analysis, (iii) making the Curated Data available to Data Recipients for research analysis via a data access application to the Data Access Committee, and (iv) secure storage.

## 1. Definitions

In this Agreement:

**"Agreement"** means the current agreement, including any amendments thereto;

**"Anonymous Information"** means information which does not relate to an identified or identifiable natural person or to personal data rendered anonymous in such a manner that the data subject is not or no longer identifiable.

**"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;

**"Collaborative Analysis"** means the production of high-level, aggregate reports, and analyses of case numbers, clinical features, treatments and outcomes in collaboration with the Data Contributor;

**"Confidential Information"** means any and all information disclosed by or on behalf of the 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, including the Data;

**“Controller”** means the legal body (the Data Contributor) which determines the purposes and means of the processing of personal data as instructed to the Processor (IDDO) through this Agreement;

**“Curated Data”** means the dataset hosted by IDDO following completion of Curation and logically or technically separated from the Raw Data;

**“Curation” or “Curate”** means the process by which the Raw Data undergoes De-Identification, verification, cleaning, standardisation and/or mapping to a harmonised format;

**“Data”** means the Raw Data and Curated Data;

**“Data Access Committee”** means the independent committee appointed to approve Data Recipient access to Curated Data;

**“Data Contributor” or “Contributor”** means the legal body that provides the Raw Data to the Platform as a Controller;

**“Data Protection Laws”** mean, as applicable, the GDPR and any local, provincial or national legislation implementing the GDPR, the UK GDPR, and any applicable national legislation on the collection, processing and sharing of personal data, in each case, any new or revised version of such laws from time to time;

**“Data Recipient” or “Recipient”** means the natural persons who request to receive the Curated Data via a data access application to the Data Access Committee, and with whom IDDO has concluded a separate data use agreement;

**“De-identification”** means the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject. De-identification goes further than Pseudonymisation to reduce the risk of re-identification in accordance with best practice, thus getting as close to Anonymous Information as possible.

**“Digital Object Identifier” or “DOI”** means a persistent identifier used to identify objects uniquely. DOIs assigned in the context of the Platform will link to metadata about the Data and instructions on how to apply for access to the Data;

**“GDPR”** means the 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;

**“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 IDDO; and
- (b) The entity or institution on whose behalf Raw Data are submitted to the Platform under this Agreement (the “Data Contributor” or “Contributor”);

“**Platform**” means the platform developed, hosted and maintained by the University of Oxford, on which Data contributed by a variety of data contributors, are collated and Curated;

“**Processor**” means a legal body (IDDO as part of the University of Oxford) which processes personal data on behalf of the Controller as instructed by the Controller through this Agreement;

“**Proposed Research**” means the research outlined in a data access application by the Recipient to the Data Access Committee;

“**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 Pseudonymised data, including personal data, submitted by or on behalf of the Data Contributor to the Platform for the purposes of being processed by IDDO as a Processor in accordance with the terms of this Agreement;

“**Third Party**” means any entity or person other than the Parties and the Data Recipient(s);

“**UK GDPR**” means the UK General Data Protection Regulation, 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, including the UK Data Protection Act 2018. Definitions of the terms of the article 4 of GDPR shall apply to this Agreement.

## **2. Submission of Raw Data to the Platform**

- 2.1 The Parties shall undertake to comply with the Applicable Regulations and Data Protection Laws in the collection, processing and sharing of Data in accordance with this Agreement.
- 2.2 The Contributor hereby grants the University of Oxford a limited, non-exclusive licence to use the Data for the purposes of (i) Curation, (ii) Collaborative Analysis, (iii) storage of the Data and, (iv) sharing the Curated Data with Data Recipients in accordance with clauses 5.3, 5.4 and 5.5, including when such sharing entails a transfer to third countries or international organisations.
- 2.3 The Contributor shall transfer the Raw Data to the Platform following execution of this Agreement.
- 2.4 The University of Oxford 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 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 that:

3.1.1 it has obtained, if necessary, all licences, permits and/or consents or waivers thereof for the collection, storage, Curation and processing of the Raw Data by IDDO, and sharing of the Curated Data by IDDO with the Data Recipients 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, if required, to submit the Data to the Platform;

3.1.3 the Data were collected in compliance with all Applicable Regulations and Data Protection Laws that apply to the Contributor; and

3.1.4 it has the right to enter into this Agreement.

3.2 The Contributor shall use all reasonable efforts not to transfer, disclose or otherwise make available any data that directly identifies a natural person to the Platform.

### **4. Processor obligations**

4.1 The Parties acknowledge and agree that, in the event that the Raw Data submitted to the Platform by the Contributor contains any personal data, the University of Oxford shall first process such personal data as a Processor of the Contributor for the sole purpose of De-identifying the Raw Data and only in respect of De-identifying such Raw Data. Without prejudice to Clause 3.2, the University of Oxford shall permanently and irrevocably De-Identify any personal data contained within the Raw Data as part of the Curation process in accordance with clause 4.2 and the de-identification procedure set forth in clause 7 and in the IDDO De-identification Procedure (<https://www.iddo.org/document/iddo-de-identification-procedure-clinical-trials>).

4.2 The University of Oxford shall:

4.2.1 process the personal data only for the purposes of the Contributor (including for the purpose of De-Identifying the Raw Data) and in accordance with the written instructions of the Contributor as Controller, unless the processing is required by applicable law to which the University of Oxford is subject, in which case the University of Oxford shall inform the Contributor of that legal requirement before undertaking the relevant processing of personal data (save where by law it is prohibited from so notifying the Contributor);

4.2.2 when transferring Curated Data to Data Recipients located in third countries or international organisations to do so in compliance with Chapter V GDPR and in

- accordance with this Agreement;
- 4.2.3 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;
- 4.2.4 ensure that the personnel and consultants working under the instructions of the University of Oxford 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;
- 4.2.5 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, including in particular and at least the measures set forth in the IDDO Technical and Organisational Measures (<https://www.iddo.org/document/iddo-technical-and-organisational-measures-toms>);
- 4.2.6 assist the Contributor, by having appropriate technical and organisational measures, to respond to any request from a data subject for exercising their data subject's rights;
- 4.2.7 when delegating the processing of personal data to a sub-processor, the sub-processor will be bound to comply with provisions relating to confidentiality and data protection at least as strict as the provisions of this Agreement, it being further understood and agreed between the Parties that the University of Oxford shall remain responsible for the conduct of any of its sub-processors as for its own conduct; the University of Oxford has the Contributor's general authorisation for the engagement of sub-processors, although the University of Oxford shall inform in writing the Contributor of any intended changes concerning the addition or replacement of sub-processors at least 14 days in advance, thereby giving the Contributor the opportunity to object to such changes prior to the engagement of the concerned sub-processor(s); Consent shall be deemed given in respect of the sub-processors listed by IDDO (<https://www.iddo.org/document/iddo-sub-processors>).
- 4.2.8 assist the Contributor in its compliance with Data Protection Laws by:
- (a) keeping personal data secure;
  - (b) notifying the Contributor as quickly as possible of any actual or suspected personal data breaches so the Contributor can notify the competent supervisory authorities and the data subjects, as applicable;

- (c) conducting data protection impact assessments when required; 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 that cannot be mitigated;
- 4.2.9 immediately inform the Contributor if instructions given by the Contributor under clause 4.2.1, in the opinion of the University of Oxford, contravene the GDPR or applicable EU or Member State data protection provisions;
- 4.2.10 at the written direction of the Contributor, delete or return personal data and copies thereof to the Contributor on termination of this Agreement unless it is required to store the personal data by law;
- 4.2.11 maintain complete and accurate records and information to demonstrate its compliance with this Agreement and shall allow Contributor or an auditor mandated by Contributor at reasonable times to audit and review the compliance with this clause 4.2;
- 4.2.12 agree to any reasonable amendment to this clause 4.2 necessary to bring this clause 4.2 and the University of Oxford's obligations in respect of the processing of personal data into line with Data Protection Laws, as amended from time to time;
- 4.2.13 keep a record of any processing of the personal data it carries out; and
- 4.2.14 at the Contributor's reasonable request make available to the Contributor evidence to demonstrate the University of Oxford's compliance with the requirements of this clause 4.2.

## **5. Data Curation and other processing to be carried out by the University of Oxford**

- 5.1 The University of Oxford is authorised, following submission of the Raw Data to the Platform to process the Raw Data in accordance with clause 4.2 and the de-identification procedure set forth in clause 7 and in the IDDO De-identification Procedure (<https://www.iddo.org/document/iddo-de-identification-procedure-clinical-trials>) as part of Curation.
- 5.2 During the Curation process, the University of Oxford may contact the Contributor for clarification of Raw Data contents.
- 5.3 Subject to clauses 5.4 and 5.5, the University of Oxford will make a description of the volumes and types of Data (called metadata) publicly available - this may include assignment of a digital object identifier (DOI) that can be posted to public inventories. The University of Oxford will share the Curated Data with Data Recipients for research purposes ("Proposed Research") following written approval from the Data Access Committee, subject to clause 5.4.
- 5.4 *The Data Contributor should choose one option, 5.4A or 5.4B when submitting data and accepting these terms:*

A) – Data Access Committee

The Data Contributor as Controller instructs the Data Access Committee to review applications to access data on its behalf. All Data Recipients approved by the Data Access Committee to access Curated Data will be required as part of the terms of the Data Access Committee approval to invite the Contributor(s) to participate in the Proposed Research. The Contributor shall have the right but not the obligation to participate in the Proposed Research. For the avoidance of doubt, the Curated Data will be shared with the Data Recipient for the approved Proposed Research even if the Contributor declines to participate in the Proposed Research. The purpose of these requirements is to inform and include the Contributor in all use of Curated Data, insofar as the Contributor wishes to be.

Or

B) – Data Contributor

The University of Oxford will submit Data Recipient requests for access to Curated Data to the Data Contributor ten working days before the University of Oxford submits such request to the Data Access Committee. During that ten working day period the Data Contributor may reply in writing to either (i) object to providing access to the Curated Data for the Proposed Research, such objection to include a rationale for objecting or (ii) agree to providing access to the Curated Data for the Proposed Research, such approval may include comments to be considered by the Data Access Committee. If the Data Contributor does not object in writing within ten working days the University of Oxford is free to submit the request for access to Curated Data to the Data Access Committee. It is the instruction of the Data Contributor as Controller that this clause 5.4B shall survive for a period of five years from the date this Agreement is entered into, whereupon it will automatically transfer to 5.4A. All Data Recipients approved by the Data Access Committee to access Curated Data will be required as part of the terms of the Data Access Committee approval to invite the Contributor(s) to participate in the Proposed Research. The Data Contributor shall have the right but not the obligation to participate in the Proposed Research. For the avoidance of doubt, the Curated Data will be shared with the Data Recipient for the approved Proposed Research even if the Contributor declines to participate in the Proposed Research. The purpose of these requirements is to inform and include the Data Contributor in all use of Curated Data, insofar as the Contributor wishes to be.

5.5 Sharing of the Curated Data by the University of Oxford with the relevant Data Recipient will be under the terms of a separate data use agreement between the University of Oxford and the Data Recipient in compliance with Applicable Regulations and Data Protection Laws, especially the one of the Contributors, and shall ensure that such data use agreement impose at least as strict confidentiality obligations for the Curated Data as those laid down in this Agreement.

5.6 The University of Oxford is also authorized to process the Curated Data as part of a



Collaborative Analysis and to store such Curated Data for a period of twenty-five years from the date of transfer of the Raw Data to the Platform, subject to earlier termination pursuant to clauses 10.2 and 10.3. The Parties may agree to extend this twenty-five year period if the Parties determine that there is a scientific need for such an extension.

## **6. Permitted use of the data**

6.1 The University of Oxford 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, including, but not limited to, research participants, health care professionals and research collaborators; or
- 6.1.2 link, attempt to link or permit a Third Party or a Data Recipient to link the Data with any other data or source of data in a manner that may enable re-identification of individuals (living or deceased) or communities associated with the Data, including, but not limited to, research participants, health care professionals and research collaborators; 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 and authorized sub-processors (including those listed in listed in Appendix 2), as well as the Data Recipient with respect to Curated Data, 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 The University of Oxford shall:

- 6.2.1 ensure the Data is processed and used in compliance with all Applicable Regulations and Data Protection Laws 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 the University of Oxford from time to time.

6.3 Notwithstanding Clause 6.1.3, the University of Oxford will report without undue delay to the Contributor, any request for access to and any actual access to personal data by public authorities. The University of Oxford shall take into account the reasonable requests of the Contributor in relation to the content of disclosure. The University of Oxford may disclose Confidential Information and/or Data to the minimum extent required by an order of a court of competent jurisdiction in the EU/EEA or any regulatory, judicial, governmental or similar body of competent jurisdiction in the EU/EEA.



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

## **7. De-identification procedure by the University of Oxford and security**

7.1 The University of Oxford shall follow the de-identification procedure set out in the IDDO De-identification Procedure (<https://www.iddo.org/document/iddo-de-identification-procedure-clinical-trials>).

7.2 The University of Oxford shall further:

7.2.1 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 the University of Oxford shall store the Data only on encrypted, access-limited, password-protected computers and/or servers. Any duplication of the Data must be fully documented such that all versions can be deleted on request or on termination of this Agreement; and

7.2.2 notify the Contributor immediately upon becoming aware of any unauthorised use or disclosure of, or access to, the Data and the University of Oxford 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 intellectual property rights (IPRs) relating thereto to the University of Oxford or any Third Party or Data Recipient.

8.2 To the extent that any IPRs in the Data do not vest automatically in the Contributor, the University of Oxford hereby assigns (by way of present and future assignment) with full title guarantee all IPRs in the Data to 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 the University of Oxford, whether in contract, tort (including negligence or breach of statutory duty) or otherwise howsoever arising.
- 9.3 The University of Oxford acknowledges that the Data is provided “as is” and the 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 the Contributor and the University of Oxford 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. Notwithstanding the foregoing, nothing in this Agreement shall exclude or limit the liability for gross negligence or wilful misconduct.
- 9.5 The University of Oxford 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 the University of Oxford’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 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 Platform, 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 the University of Oxford shall (unless explicitly approved otherwise by the Contributor in writing) securely destroy the Data and all Confidential Information in its possession or control and shall certify in writing to Contributor that it has done so. Compliance with this Clause shall not require the University of Oxford 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 Submission*), 4.2 (*Processor Obligations*) for as long as the University of Oxford processes, has access to, or otherwise retains personal

data on behalf of the Contributor, 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 (*General*), 12 (*Notices*), 13 (*Interpretation*), 14 (*Disputes*) and 15 (*Governing Law*) shall remain in force.

## **11. General**

- 11.1 This Agreement may only be amended in writing signed by duly authorised representatives of the University of Oxford and the Contributor.
- 11.2 The University of Oxford 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.
- 11.3 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.
- 11.4 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.
- 11.5 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.
- 11.6 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.

## **12. Notices**

- 12.1 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:
  - 12.1.1 in the case of the University of Oxford: [info@iddo.org](mailto:info@iddo.org)
  - 12.1.2 in the case of Contributor: the email address provided by the Contributor on acceptance of this Agreement
- 12.2 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.

### **13. Interpretation**

13.1 In this Agreement:

13.1.1 references to the singular include the plural and vice versa;

13.1.2 where the word “including” is used it shall be understood as meaning “including without limitation”; and

13.1.3 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.

### **14. Disputes**

14.1 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 15.

14.2 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.

### **15. Governing law**

15.1 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.