IDDO Data Access Guidelines

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A. DEFINITIONS

Access – transfer of Platform Data to an approved Data Requestor.

Data Access Application – information submitted for consideration by the Data Access Committee for the purpose of gaining access to Platform Data (see Application Form in Appendix 1).

Data Access Request Evaluation Form (DARE) – an evaluation form used by the DAC to assess any requests to access DAC controlled data.

Data Contributor – any individual or organisation who has submitted primary Data for inclusion in the IDDO Platform.

Data Requestor – any individual or organisation requesting access to Platform Data and who will be actively involved with the proposed research.

Data Transfer Agreement (DTA) – an agreement between the Data Requestor and the Platform host

1 The IDDO DAC will manage data access across the IDDO research themes of i) Malaria (WWARN) ii) Visceral Leshmaniasis (VL) iii) Schistosomiasis/Soil Transmitted Helminths, and iv) Chagas.

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institution (University of Oxford) to establish the terms and conditions of Data transfer.

**Data Subject (or Subject)** – an individual from whom Data have been collected or to whom Data relates.

**Data Sharing Platform (the Platform)** – a collection of data, managed by a governance and ethical framework to responsibly promote the availability of data for sharing and re-use in order to generate new knowledge.

**Independent Data Access Committee (DAC)** – a group of appointed experts who make decisions regarding applications for access to Platform Data.

**Intellectual Property** - all intellectual property, patents, trademarks, design registrations, copyrights, specifications, drawings, designs, data, database rights, information, ideas, methods, patterns, know-how and/or inventions including without limitation, testing and validation reports, process parameters and documentation, and regulatory registrations and supporting files, whether patentable or not, arising from or related to or useable in connection with the Platform data.

**Inventory** – an openly available list of all Data included on the Platform.

**Platform Data (or Data)** – demographic, health, biometric, genomic or other information on individuals, samples, medicines, communities, conditions or organisations submitted to the Platform.

**Publication** - any abstracts, reports, external communication, websites, presentations or other peer-reviewed scientific publications that contain outputs directly or indirectly related to the Data.

**Research** - any medical, biological, laboratory and research activities (including but not limited to scientific research, operational research, epidemiology, clinical research, program research, evaluations, retrospective program analysis etc.) involving the collection of information about a particular subject or research primarily and substantially aimed at understanding or treating any pathogen, disease or condition.

**Research Outputs (or Outputs)** - any information, data, and/or results generated in or arising from use or analysis of the Data.

**Secretariat** – the entity responsible for hosting the Platform including responsibility for the technical architecture, data curation, data security, data management and transfer, budget administration, and Platform website development and management. The Secretariat will support the development and execution of Platform proposals, policy and approvals and will support administration for the Data Access Committee.

**Terms of Submission** - A legal document executed between the data provider and data recipient (in this case the data contributor and Oxford who will hold the data), to agree the terms under which the data are submitted to the platform.

**Theme** – An area of research within IDDO categorised by a research community coming together to address knowledge gaps and save lives.

### B. OVERVIEW

The Infectious Diseases Data Observatory (IDDO) is a scientifically independent, multi-disciplinary coalition of the global infectious disease community. It accelerates better treatment and control of poverty-related infectious diseases by generating research evidence through data re-use, putting the communities most affected at the centre of its global collaborations.
IDDO (https://www.iddo.org/) is based at the University of Oxford and builds on and incorporates the pioneering work of the WorldWide Antimalarial Resistance Network (WWARN) (https://www.wwarn.org/), a unique, decade-long collaborative data-sharing framework that proved it was possible to produce policy-changing scientific evidence from historical data, benefiting the health of millions. WWARN is now part of the IDDO portfolio.

Individuals who contribute data to IDDO can decide between two data sharing models - retain decision-making power each and every time a data re-use analysis is done (Contributor Controlled CC) or delegate decisions about data access and re-use to the IDDO Data Access Committee (DAC) – DAC controlled.

These Data Access Guidelines are specific to datasets where access decisions have been devolved to the DAC. Access to the other datasets is not regulated by these terms.

The IDDO Data Access Committee reviews, prioritizes and makes decisions regarding the approval of applications for access to platform data across the disease themes of Malaria (WWARN), Visceral Leishmaniasis (VL), Schistosomiasis/Soil Transmitted Helminths STH, and Chagas2. This document describes the guidelines and process for access to IDDO data, and describes the basis on which the DAC will make decisions about applications for data access. This document is developed and amended by the DAC and provides the principles of access, details of eligibility for access, process for applications and decisions. Conditions for use of transferred datasets are specified in a separate Data Transfer Agreement (DTA). See Appendix 1.

C. PRINCIPLES OF ACCESS TO PLATFORM DATA

While there is no internationally accepted policy framework to govern data sharing, IDDO has developed the following principles to guide the DAC’s decision regarding access to data. The IDDO DAC will consider for approval applicants that propose to:

• Deliver research that addresses knowledge gaps of importance to those affected by or at risk of emerging and poverty-related diseases;
• Operate in a transparent manner and promote equitable collaboration which recognizes and protects the interests of those who generate the data;
• Protect the rights and privacy of individuals and communities from whom the data originates;
• Conduct research which contributes towards improving research capacity, policy and health in regions affected by or at risk of emerging and poverty-related diseases.

D. PROCESS OF ACCESSING IDDO DATA

Published and unpublished data are submitted to the IDDO platform by the research, health and humanitarian communities under the Terms of Submission. Via these Terms, contributors attest to their authority to submit the data, and their compliance with the necessary ethical and legal requirements. The IDDO Platform anonymises, curates and securely stores data in its repository.

IDDO makes available on its websites (both IDDO and WWARN) data inventories listing which data is

2 The remit of the IDDO DAC may expand with time, as new IDDO themes mature into the data access phase and have all the necessary technical, governance and ethical frameworks in place.
accessible to researchers for data analysis and re-use. These inventories indicate whether permission for access needs to be granted by the Data Contributor (Contributor Controlled, CC) or by the DAC (DAC Controlled).

The Data Requestor completes a Data Access Application Form (see website) and requests for accessing data for studies that have devolved access decisions will be reviewed by an independent Data Access Committee.

DAC members are nominated by a process of open nomination by the research community. The DAC is chaired by TDR, the Special Programme for Research and Training in Tropical Diseases, hosted by the World Health Organization (WHO/TDR). Data will be sent to those approved by the DAC after the execution of a Data Transfer Agreement which outlines the terms of data use.

**Timelines – See Figure 1**

1. The Data Requestor completes a Data Access Application Form and submits it to IDDO.
2. The IDDO Secretariat aims to send the Requestor a confirmation of Data Access Application Form receipt within one (1) week of submission.
3. IDDO Data Managers and an IDDO Statistician will review the application to understand the feasibility of the proposed project based on the data sets requested and the variables available in the IDDO repository (the repository only contains data submitted by the Contributor). In the event that the required variables are not available, the data Requestor will be notified within one (1) month of submission.
4. The IDDO DAC aim to review and respond to all requests for data within 2 months from receipt of the completed Data Access Application Form.
5. Following approval of data sharing, IDDO will provide Requestors with a response timeline to receive the curated data. If an application is not approved, feedback will be provided as soon as possible.
6. In the event that datasets that have not yet been curated are requested (such as newly supplied data sets, or very old datasets), Data Requestors will have the following options if their data request is approved:
   - to receive datasets that are already curated immediately *(if this option is chosen, the uncurated data sets will not be available at a later date)*;
   - to receive all datasets at a later date on completion of all curation.

**E. DATA ACCESS GUIDELINES**

1. Terms of data access

1.1. Eligibility of the Requestor

Data is accessible to researchers working in a relevant field and who have a formal affiliation to an institution with a remit including health, research or academic pursuit, and with legal status which includes the scope to sign the Data Transfer Agreement (Appendix 1). The Requester should have completed a PhD or have equivalent research experience and have demonstrable understanding and expertise to carry out the proposed work. The Data Requestor should be actively involved in the

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3 For the purposes of accessing IDDO data, IDDO staff are considered Data Requestors and must follow the same application process as outlined here.
proposed research and be able to attest that sufficient funding and resources to perform the proposed research have been secured for this purpose. The DAC will consider potential impact of any conflicts of interest declared in the application.

1.2. Eligibility of the Research Proposal

Research proposals must be scientifically sound with adequate methodology to answer the question and should address a knowledge gap of value or potential value to malaria endemic communities, and/or to wider public health. The selected Data Subjects, populations and requested Data must be appropriate for the investigation.

1.3. Ethics and other approvals

Whilst secondary data analysis does not always require ethics approval, the DAC will rely on Data Requestors to indicate that they have complied with all and any requirements for ethics and regulatory approvals required in their institutions or jurisdictions.

2. Terms of data use

2.1. Data Transfer Agreement

A Data Transfer Agreement (DTA) with University of Oxford as outlined in Appendix 1 must be signed by the appropriate signatory from the Data Requestor’s institution before Data are transferred to the Requestor.

The breach of any of the terms outlined in the DTA will result in a withdrawal of approval to access and/or use the Data and may result in recourse via the signatory institution.

2.2. Transparency

2.2.1. A summary list of proposals received and the outcome of the review will be listed on the IDDO and WWARN websites.

2.2.2. Summary information on all accepted data proposals will be made publicly available through the IDDO and WWARN websites.
Contributors choose from two data sharing models: [1] Contributor-controlled data access or [2] Data Access Committee (DAC) managed access.

1. **Contributor controlled data access**
   - Request for data access sent to Data Contributor within 1 month of submission.
   - Contributors respond to request, **response time unknown**.

2. **DAC managed access**
   - Request for data access sent to DAC within 1 month of submission.
   - DAC evaluates application against **Data Access Request Evaluation Form**. Feedback given to Data Requestor within 2 months of submission.

If data access granted, Data Requestors have the following options:
- to receive datasets that are already curated immediately (if this option is chosen, the un-curated data sets will not be available at a later date)
- to receive all datasets at a later date on completion of all curation

*The Terms of Submission is a legal agreement between the University of Oxford and the Data Contributor host institution.

**The Data Transfer Agreement is a legal agreement between the University of Oxford and the Data Requestor host institution.

_outputs are reported back to IDDO*