

IDDO Platform: Data Access Guidelines

A. STATEMENT OF PURPOSE

This document describes the guidelines and process for access to data hosted on the IDDO Platform, and describes the basis on which the IDDO Data Access Committee (“DAC”) will make decisions about applications for data access. The Data Access Guidelines are developed with the IDDO DAC, who follow these Guidelines when evaluating applications to access data held on the IDDO Platform. Conditions for use of datasets approved for release are specified in separate data use agreements signed between Data Recipients and the University of Oxford, as the legal entity that hosts the IDDO Platform.

B. OVERVIEW

[The Infectious Diseases Data Observatory](#) (IDDO) is a scientifically independent, multi-disciplinary coalition of the global infectious disease community. It supports science in countries aiming to reduce their burden of infectious diseases by generating research evidence and supporting health policy development through data reuse, putting communities most affected at the lead of its global collaborations.

Individuals who contribute data to IDDO are encouraged to delegate decisions about data access and reuse to the IDDO DAC, which operates as expert-led sub-committees associated to IDDO’s main disease themes that currently make data available for research: **Malaria (WWARN), COVID-19, Ebola, visceral leishmaniasis (VL), schistosomiasis and soil-transmitted helminthiasis.**

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). DAC operates in accordance with the DAC Terms of Reference (ToR), agreed to and reviewed periodically by DAC members, usually in line with membership terms (3 years).

C. PRINCIPLES OF ACCESS TO DATA

The IDDO DAC will consider for approval applicants that propose to address the following aims:

- deliver research that addresses knowledge gaps of importance to those affected by or at risk of infectious diseases of poverty and emerging infections;
- protect the rights and privacy of individuals and communities from whom the data originate;
- operate in a transparent manner and promote equitable collaboration that recognizes and protects the interests of those who generate the data; and
- conduct research which contributes towards improving research capacity, health and policy in regions affected by or at risk of infectious diseases.

Data will be released to those approved by the DAC after the execution of a data use agreement which outlines the contractual terms of data use.

Promotion of Access

The role of the DAC is to provide an independent decision-making committee to evaluate and decide whether requests to access data are consistent with the Data Access Guidelines and respond accordingly to applicants. If an application complies with these Guidelines, and there are no concerns of scientific value or ethics, then the application will be approved.

Conflict of Interest

Each co-applicant on an application must detail any existing or perceived conflicts of interest according to the definitions outlined in the ICMJE policy:

<http://icmje.org/recommendations/browse/roles-and-responsibilities/author-responsibilities--conflicts-of-interest.html>. All co-applicants will agree to notify the DAC and Secretariat of any changes.

D. DATA ACCESS PROCESS

The submission of published and unpublished data to IDDO is governed by legally-binding terms of submission. For the full committee procedures and definitions, please refer to the Data Access Committee Terms of Reference.

Approval

The data access process is presented here in summary.

- The Data Requestor completes a Data Access Application Form (see Annex 1) and lists requested data.
- There is no fee or other cost for Data Requestors to access the Platform Data following submission of the completed application form.
- The IDDO Secretariat works with the Requestor to ensure that the Data Access Application Form is complete before forwarding to the DAC for review.
- The DAC can decide to:
 - Approve the application;
 - Approve with conditions, subject to the Data Requestor obtaining funding and/or necessary approvals;
 - Reconsider the application, asking for further clarification or amendment by the Data Requestor;
 - Reject the application, if the application is not able to meet these Guidelines.
- The DAC will provide written justification for all rejected applications.

Rejected applications and those for which amendments are requested will be reconsidered if the issues raised by the DAC are addressed in a revised application. Disputes and/or appeals regarding the data access decisions will be managed by the Chair or his delegate as appointed.

A response from the DAC will be received in 2 weeks depending on the nature of the request. Research that is urgent to address an active public health emergency, and following the agreement of the DAC Chair, will receive a response within 3 business days.

All Data Recipients approved by the DAC to access Curated Data will be required as part of the terms of the DAC approval to invite the Data Contributor(s) to participate in the Proposed Research and/or to acknowledge Data Contributors in the Proposed Research as stipulated within Schedule 1 of the data use agreement.

Post-approval

Following approval for access to data, there are times when a data access application needs to be amended following DAC review.

New members are added to the Research Team

Data use for research is limited to members of the Research Team listed in the application to access data. The data use agreement allows for new additions to the Research Team to be added, which is accomplished by providing the Secretariat with an updated application form, to be appended to the original data use agreement.

Additional data is required

If the DAC has completed their review, no further amendments can be made to the existing application without additional review (the only exception being the addition of new Research Team members described above). If any further data are added to the research proposal later, this will require the DAC Chair to approve the amended application. This process can only happen if no change has been made to the research question and methodology. Significant changes to the application, such as changes to the research question or methodology, will require a new application to the DAC.

E. REVIEW CONSIDERATIONS

Applications will be evaluated according to the following criteria.

Scientific Value

The DAC will ensure that the proposal has scientific value by verifying that the research question:

- is in line with research areas highlighted by published global research agendas or those from diseases-affected communities, or has received a credible and favourable scientific peer-review;
- addresses a knowledge gap and avoids duplication and unnecessary competition;
- benefits the wider public health community.

Plans to publish and disseminate the research results must enable open access to the results

Scientific Validity

The Data requested must be capable of answering the research question.

The methodology proposed to answer the research question must be sound.

Applications to the Platform must not request more than the data necessary to answer the research question – each variable requested must be required for the successful completion of the research (in line with GDPR principles of proportionality and minimization).

In order to avoid unnecessary duplication, the DAC may reject an application or return it for reconsideration if the application is considered to be significantly overlapping with ongoing or completed research using the Data from the Platform.

Researchers

Access to data is limited to Data Requestors working in a relevant field and with a formal affiliation to a health, research, humanitarian, government, inter-government or academic institution with

legal status.

The Data Requestor will have either an academic record consistent with execution of the proposed analysis, or the support of a supervising co-applicant with appropriate expertise.

The Data Requestor will attest that sufficient funding to perform the proposed research has been secured or is being sought for this purpose.

The Data Requestor will not have previously violated any of the requirements for data access outlined in these Guidelines or any data use agreement.

Ethics

The DAC must be satisfied that there are no concerns with respect to the ethical aspects of the application. The DAC will consider all applicable ethical and legal regulations, including without limitation: (i) of the country where the data have been collected or originate from; and (ii) international best standards and rules relating to medical obligations, data protection and data access.

Whilst secondary data analysis does not always require ethics approval, the DAC will rely on Data Requestors to provide evidence to the Committee that they have complied with all and any requirements for ethics and regulatory approvals required in their institutions or jurisdictions, including proof of any ethics committee review waiver.

All required scientific and ethical reviews and/or approvals, including Data Requestor's Institution, must be obtained before any Data are transferred.

Collaboration and Knowledge Sharing

The IDDO Platform and its partners operate under a mandate to build local research capability, particularly in low-resource settings, where infectious diseases have a disproportionate impact on already-fragile health systems. Applications should provide details of how the research will involve local partners and/or bring benefit to these communities and some examples of such initiatives are included in the Data Access Application (Annex 1).

F. DATA USE AGREEMENT

A data use agreement with the University of Oxford must be signed by the appropriate signatory from the Data Requestor's institution before Data are released to the Requestor. Where the Lead Investigator is employed by the University of Oxford, the appropriate signatures are executed by the respective Principal Investigators using a cover letter that acknowledges the terms of the IDDO data use agreement. In all cases, the data use agreement imposes obligations on the Data Requestor that are intended to ensure compliance with the key principles underpinning the Platform.

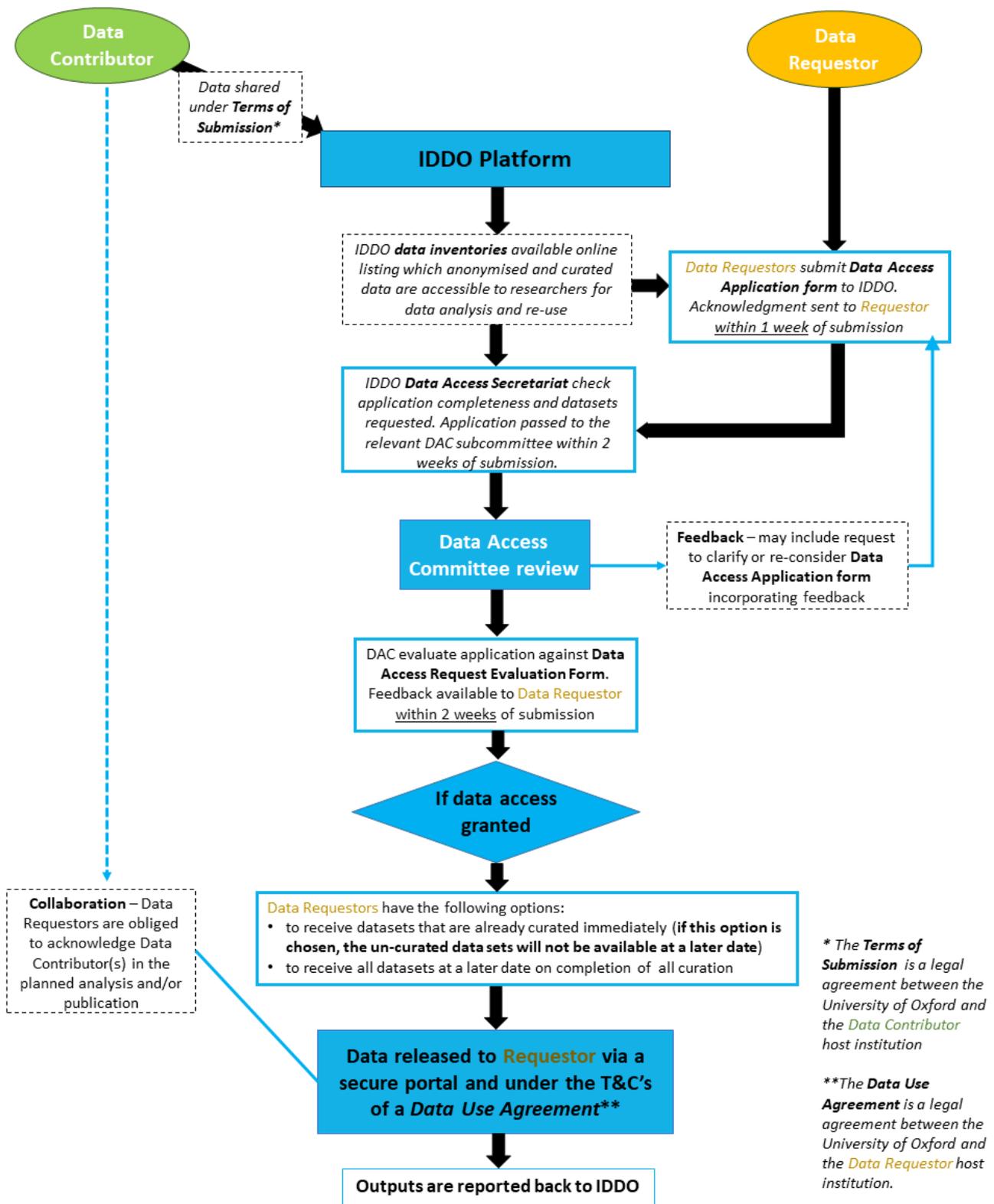
The breach of any of the terms outlined in the data use agreement will result in a withdrawal of approval to access and/or use of the Data.

G. TRANSPARENCY

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

Final versions of approved data access applications will be made publicly available through the IDDO website.

The IDDO Data Access Journey



Appendix 1: IDDO Data Access Application Form

The Data Access Application Form is used by IDDO's independent data access committee to evaluate your proposal and make data access decisions. Please review the relevant [Data Access Guidelines](#) and the IDDO [Data Use Agreement](#) before completing this form. A complete application should address all of the Review Considerations outlined in the Data Access Guidelines. **Note that the details of all approved applications will be made publicly available on the IDDO website.**

Complete all sections of this form fully and return with any supporting documentation to:

Malaria and neglected tropical diseases: dataaccess@iddo.org

COVID-19 and Ebola: emerging-infections@iddo.org

Please note that according to IDDO's standard operating procedures, any changes to the Research Team, their conflict of interest, adding and removal of data variables or studies in the request, or changes to research objectives or methodology will require that the Data Access Committee re-review and re-approve the data request.

SECTION A: LEAD APPLICANT / RESEARCH TEAM INFORMATION	
Lead Applicant Details	
Title (Prof, Dr)	
First name (given name)	
Surname (family name)	
Gender	
Position at employing organisation / institution	
ORCID ID https://orcid.org/ or URL to academic profile	<i>[if no ORCID or URL, please attach a short academic CV]</i>
Email	
Employing Organisation/Institution <i>Institution with a remit including health, research or academic pursuit, and with legal status which includes the scope to sign the Data Use Agreement.</i>	
Institution Name	
Department (if applicable)	
City	
Country	

Has your institution reviewed and agreed to execute the Data Use Agreement if your application is approved?	YES/NO (delete as appropriate)
Co-applicants (Research Team) <i>ALL individuals accessing data must be listed on this form. Any later additions must be notified to IDDO and the Data Access Committee. Add rows as necessary.</i>	
1. Name / Title	
1. Position / Role in analysis	
2. Organisation/Institution	
2. Name / Title	
2. Position / Role in analysis	
2. Organisation/Institution	
3. Name / Title	
3. Position / Role in analysis	
3. Organisation/Institution	
Conflicts of Interest <i>List details of any existing or perceived conflicts of interest (financial or non-financial) that exist relating to the use of the requested data by the data requestor and/or co-applicants (see ICMJE.org for the definition of conflicts of interest).</i>	
SECTION B: RESEARCH PLAN	
Title of Proposed Research	
Is this a re-submission of a previous application to IDDO that has already been reviewed?	<i>[If yes, provide the submission date of the previous application]</i>
Summary of Research in Lay Language <i>Suggested maximum 200 words</i>	
Summary of Research Objectives and Scientific Value <i>Suggested maximum 400 words</i> <i>Scientific value is demonstrated by research objectives that are:</i> <ul style="list-style-type: none"> • <i>in line with research areas highlighted by a published global research agenda</i> • <i>address knowledge gaps of importance to those affected by emerging and poverty-related diseases while avoiding duplication and unnecessary competition</i> • <i>benefit the wider public health community and contribute towards improving research capacity, policy and health in disease-affected communities</i> 	

Primary and Secondary Outcome Measures

Suggested maximum 200 words

Proposed Methodology and Statistical Analysis Plan

For each main outcome measure, please describe:

- *analysis population*
- *measures of effect to be reported*
- *statistical methods with relevant details such as name of test/regression model*
- *inference method*
- *covariate adjustments*
- *subgroup analyses*
- *adjustment for multiple studies and assessment of heterogeneity*
- *model fit evaluations*
- *sensitivity analyses*
- *sample size/power considerations*

Ethics

Suggested maximum 300 words.

Provide details of any approvals required by your institution to undertake this work, list reference numbers of any approvals, or provide clear evidence as to why no approvals are required (e.g. an extract of relevant the policy from your institutional ethics review board).

In addition, please give examples of which ethics guidelines you will be following with respect to delivering this project (e.g. you may wish to refer to general guidance such as the CIOMS/WHO [International Ethical Guidelines for Health-related Research Involving Humans](#), domain-specific guidance such as the FATML [Principles for Accountable Algorithms](#), or guidance specific to the type of research you are undertaking such as the Nuffield Council on Bioethics [Research in Global Health Emergencies: Ethical Issues; London, 2020](#) (as applicable).

Publication and Dissemination Plan

Suggested maximum 300 words.

*Provide a clear **timeline** for the research, including a date for submission of publication(s) and dissemination of research findings (the submission date will be used to define the **Term** for data use in the **Data Use Agreement**, which lasts for two years).*

*Provide details of **plans for authorship/acknowledgement of data contributors**. Plans to publish and disseminate the research results must enable **open access** to the results.*

Collaboration and Knowledge Sharing

Suggested maximum 300 words.

Where the application requests data from low-resource settings, please include details of either:

collaborative partnerships with these research communities, a strategy to support an appropriate capacity building initiative and/or share knowledge directly with regional/national health authorities.

Funding

Suggested maximum 100 words.

Provide confirmation that this research is adequately funded/resourced. Please name the source or sources of funding.

Scientific Review

Suggested maximum 200 words.

If the project has been scientifically reviewed outside of your Research Team named above, please provide details. This could be by a funder/donor or review committee, or even another expert at your institution. If this has not taken place, please detail how your team has sufficient expertise/experience to deliver this work.

SECTION C: DATA

Data Required

Please provide a list of studies, data variables and/or description/parameters for the data you require to complete your analysis. Include parameters to check eligibility criteria (e.g. pregnancy status).