IDDO Data Access Committee Terms of Reference

1.	Date Approved and Governing Body	These Terms of Reference (ToR) will be agreed by the Infectious Diseases Data Observatory (IDDO) Data Access Committee (DAC). The IDDO DAC is an independent body composed of expert-led subcommittees and chaired by a representative of TDR, the Special Programme for Training and Research in Tropical Diseases, hosted by WHO. Where external guidance is required by the IDDO DAC, the IDDO Board is available for consultation.
		The IDDO DAC formally adopted these ToRs on 16 January 2023 following their meeting on 27 October 2022 and subsequent period of review for all members.
2.	Purpose	The IDDO Data Platform ("Platform") has been established to accelerate better treatment and control of infectious diseases by strengthening research and generating evidence for policy impact through equitable data reuse. The Platform hosts several disease research themes currently offering access to data: **Malaria (WWARN), COVID-19, Ebola, visceral leishmaniasis (VL), schistosomiasis and soil-transmitted helminthiases**.
		The Platform fulfils its purpose through:
		- curation (including de-identification, standardisation and cleaning) of submitted data for each disease research theme; - management of requests for access to de-identified research datasets; - promotion of scientific collaboration and equitable access to data across diverse research themes focusing on disease-affected communities.
		The purpose of the DAC is to:
		- provide an independent decision-making committee to evaluate and decide whether requests to access data from the Platform are consistent with the Data Access Guidelines and respond accordingly to applicants; - liaise with the IDDO Data Access Secretariat to define the status of the data sets to be released; - consider the Platform's Conflict of Interest Policy when making decisions regarding access; - if needed, prioritize applications according to the Data Access Guidelines.
		In the execution of its responsibilities and decision-making, the IDDO DAC will apply the principles that govern the use of the Platform, in line with the Data Access Guidelines, the mission of IDDO, and the research objectives of each disease research theme.
		The members of the IDDO DAC will ensure that the highest standards of security and privacy are maintained whilst facilitating the ethical, equitable and rapid access to data. Applications for access to data and the deliberations of the IDDO DAC are considered confidential until public release as set out below.

3. Membership	•	The IDDO DAC shall comprise no fewer than 12 members, with no fewer than 6 members in each of its two current subcommittees: [1] emerging infections and [2] malaria and neglected tropical diseases. It will be constituted with representation from across the Platform's disease research themes and diverse regions affected by outbreaks of emerging diseases and endemic regions for malaria and neglected tropical diseases; and
	•	a representative balance of skills and expertise in clinical research, data protection and management, ethics in research and emergency public health response, benefit sharing and community engagement.
	The DAC will endeavour to avoid gender and geographical imbalances.	
4. Eligibility	Members must agree to abide by the Conflict of Interest Policy and the governance framework for the Platform.	
	The Chair is appointed as a representative of TDR for the whole of the IDDO DAC. Other members will be appointed by the Chair in their personal capacity, on the basis of their individual expertise.	
5. Proxies	Members cannot appoint a proxy. The exception will be for non-English speaking IDDO DAC members who have the option to appoint an English-speaking named proxy. The proxy will come from the DAC member's own institution and will assist in the data access applications, IDDO DAC meetings and correspondence.	
6. Membership Term	The IDDO DAC members can hold their position for 3 years, and can be re-elected for a maximum of 3 terms. Appointment to the IDDO DAC will be staggered in order to ensure continuity of membership where possible.	
7. Resignation	Members are free to resign their position with immediate effect. Where possible, 3 months' notice should be given.	
8. Revocation	Membership to the IDDO DAC can be revoked or limited by the IDDO Board for professional misconduct and/or a breach of the Conflicts of Interest Policy, or any other part of the Platform governance framework by unanimous decision of the IDDO Board.	
	IDDO DAC members are asked to be active in their participation on the Committee to ensure rapid review and turnover. Members who respond to less than 20% of applications within a 6-month period may be asked to reconsider their involvement in the IDDO DAC.	
9. New Members	Members will be selected through an open nomination process and decision by the Chair. Current IDDO DAC members, IDDO collaborators and partners, and the general public have equal opportunity to make nominations. Calls for new nominations may also be included in IDDO public communications.	
10. Chair	A Chair shall be appointed by TDR. This position will be held on a 3-year basis. The Chair can be re-appointed and can serve a maximum of 3 terms.	
	The Chair can temporarily delegate their responsibility to a Vice-chair or another IDDO DAC member when appropriate, for instance if they are unable to attend a meeting or if there is a perceived conflict of interest. Delegation will be recorded in the meeting minutes.	

	The Chair will be responsible for dealing with urgent matters that arise between scheduled meetings of the IDDO DAC.
11. External Observers	External observers/advisors who offer expertise in specific issues relevant to the applications being considered may be consulted when approved by the IDDO DAC Chair. External observers will not participate in decisions or votes and may be requested to sign non-disclosure agreements as necessary.
12. Administration	The Data Access Secretariat is comprised of staff from IDDO, hosted by the University of Oxford. The Data Access Secretariat will provide administrative services to the IDDO DAC. It will receive and distribute communications on its behalf, and manage and coordinate required meeting activities in accordance with the Data Access Secretariat Terms of Reference.
13. Quorum	No business shall be transacted at any meeting of the IDDO DAC unless a quorum of its members are present or available to contribute feedback, and no review of applications to access data shall be approved until a quorum responds. A quorum is at least 3 members and should include at least one expert from the disease research theme the application is related to.
	The Chair shall NOT count towards quorum but their opinion may be requested on either an urgent basis or where there is discordance of opinion among the reviewers. The Chair can also act via Vice-chair(s) appointed from the subcommittees.
14. Frequency of Meetings	The IDDO DAC will meet initially via videoconference to approve relevant governance documentation, with subsequent review decisions made remotely via email or other electronic means and/or in-person meetings as appropriate and financially feasible.
	A meeting via teleconference may be called at any time when requested by the Chair or by at least two members of the IDDO DAC upon reasonable notice to other members.
15. Operation of the Data Access Committee	The IDDO DAC may regulate its own procedures subject to the provisions of these Terms of Reference.
	The Data Access Secretariat shall circulate notice, agenda and meeting materials for any DAC meeting at a reasonable time in advance, stating the date, time and details of the meeting.
	Any member is welcomed to place an item on the agenda for an IDDO DAC meeting. Advanced notice to the Data Access Secretariat is appreciated when possible.
	The Data Access Secretariat shall keep minutes of the proceedings of any meeting of the IDDO DAC and distribute minutes to all members.
	All members of the relevant subcommittee will receive a copy of all requests for data access within that theme. Where needed and approved by the Chair the request for data access can be escalated to a wider number of IDDO DAC members, specifically if their wider research expertise is of relevance to the application's research.
	Collective decision-making will be enabled using a secure online system, enabling an efficient review turnaround. The DAC aim to provide responses to requests for review of data access applications within 2 weeks. Research that is urgent to address an active public health emergency, and following approval by the DAC Chair, will receive a shorter response time of 3 business days. Applicants will be notified of the

		outcome of their application as soon as possible, and within 6 weeks of their application being submitted to the IDDO DAC for review.
		Each party will execute its duties in good faith.
16.	Duties: Decision Making and Responsibilities	Members will be notified via email when a new application is submitted for review. Members review applications within their subcommittees, aligned to their area of disease expertise, where relevant. Occasionally, members may be approached for their input on an application from another disease theme or subcommittee when that is deemed particularly relevant to their area of expertise.

Members can vote to approve, conditionally approve, reconsider or reject an application. Votes to reconsider or reject must be accompanied by a rationale. All votes and rationale will be visible to all members. Each application will require 3 votes only to determine the decision of the IDDO DAC. Voting will be terminated after the first 3 votes, except in the cases as outlined below.

An application that receives 3 approval votes within the review period agreed by the IDDO DAC (2 weeks) and no reconsideration or rejection votes will be approved.

An application that receives more than 1 vote for rejection or reconsideration within the first 3 votes will be returned to the applicant with appropriate feedback based on the rationale given by members. The contents of the response will be formulated by the Data Access Secretariat, with input and endorsement of the Chair when required.

If an application receives a single vote for rejection or reconsideration within the first 3 votes:

- all members of the relevant subcommittee will be notified that further review is needed;
- voting will remain open for members who did not already vote until 2 more additional votes are received;
- if only a single vote for reconsideration has been received in both rounds, the Chair will make an executive decision whether the application's overall status changes to Reconsider or it remains as Conditional Approval based on consideration of all votes and rationale submitted. The Chair may consult any IDDO DAC member to assist him in making the final decision.

The Data Access Secretariat will work with Data Requestors to ensure that DAC feedback is adequately incorporated so that re-consideration of amended data access applications by the IDDO DAC only occur once. The Data Requestor will retain the option of submitting a new application incorporating a substantially modified research proposal in the future, and that application will be processed as an new, independent submission for access to data.

Applications that are initiated but not progressed to the IDDO DAC review stage within 3 months will be closed, and can be re-submitted at a later date.

When meeting, the IDDO DAC shall use best endeavours to take decisions by consensus (where all those present in the meeting agree). If consensus on any decision cannot be reached, and unless the IDDO DAC decides otherwise, its decisions shall be taken by a simple majority. Where there is no majority, the Chair shall have the casting vote.

Each individual member has one vote. |

		The DAC shall have the following responsibilities:
		- to oversee all research applications to access data from the Platform including reviewing, approving, denying and requesting further details on applications in accordance with these ToR and the Data Access Guidelines, and providing written responses to applicants; - if deemed useful by the IDDO DAC, to refer the application for external advice by a subject-area expert (selected by IDDO DAC members and approved by the Chair) to provide an opinion to inform the IDDO DAC's decision; - to define the data sets to be released with assistance from the Data Access Secretariat; - to provide regular input to the IDDO Board and the Data Access Secretariat on emerging issues in data access and any implications for Platform strategy and policy; - to seek advice from the Data Access Secretariat when there is a need for input on the prioritization of requests in accordance with the Data Access Guidelines due to an influx of proposals; - to refer to the Data Access Secretariat any applications that would benefit from an evaluation by the IDDO Board, specifically: - applications to access data that result in irreconcilable disagreement amongst DAC members; - if the DAC considers the application needs, or would otherwise benefit from, the input of the IDDO Board; - determine any variance in reporting requirements for those granted access to data; - proactively engage stakeholders where appropriate.
17.	Principles, Ethics Approach and Accountability	The IDDO DAC will operate a fair, transparent, equitable, efficient, and well-governed system to make data accessible in order to facilitate research and encourage rapid publication. The IDDO DAC, with assistance from the Data Access Secretariat, will review all data access requests to ensure compliance with the Platform's Data Access Guidelines, the rest of the Platform's governance framework, ethical approvals and all applicable laws, governmental rules, regulations, good practices and guidelines, 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 confidentiality, medical ethics, privacy, medical research, data protection and data access, including without limitation the duties to not cause harm to individuals or groups, to respect patients' autonomy, patient confidentiality and the patient's right to informed consent. Public health ethics and global emergency ethics considerations will also be considered as appropriate.
18.	Interests of Data Access Committee Members	All members of the IDDO DAC shall abide by the Platform's Conflict of Interest Policy and declare any interests in advance of joining the DAC using the Declaration of Interests form. This will be reviewed annually. The Chair of the IDDO DAC will seek verbal confirmation at the start of any meeting that the Declaration of Interests of each member is current and up to date, and in respect to the items of business on the agenda. It is the duty of each member of the

	IDDO DAC to declare interests not only at the start of meetings but as and when they arise in accordance with the Conflict of Interest Policy.
	Should any conflict arise, these shall be managed in line with the procedures outlined in the Platform's Conflict of Interest Policy. Applications from IDDO-associated persons, the Data Access Secretariat, DAC members, previous members/representatives or associated persons will be managed in accordance with the Conflict of Interest Policy and any IDDO DAC or other governance body member/representative with a conflict or potential conflict shall be excluded from decisions on the relevant application in accordance with the Conflict of Interest Policy.
19. Reporting Responsibilities	Titles, dates and applicant institution for all approved applications, as well as records of all IDDO DAC policies, procedures and membership shall be available on the Platform website as soon as reasonably possible after such application/decision is made.
20. Conduct of the Data Access Committee	The IDDO DAC shall keep these Terms of Reference under review. Any changes to these Terms of Reference may be made with unanimous support of IDDO DAC membership.

APPENDIX 1: Terms and definitions used in the Data Access Guidelines and IDDO DAC Terms of Reference

Access – enabling access to Platform Data by an approved Data Requestor.

Data – refers to the curated data transferred from the Platform following approval by the IDDO DAC.

Data Access Application – information submitted for consideration by the IDDO DAC for the purpose of gaining access to Platform Data for research.

IDDO Board – means the IDDO Advisory Board that governs IDDO's strategic direction and activities. Members are drawn from academia and non-governmental organisations working in the regions where IDDO's research themes are endemic, and are selected based on their international expertise and standing. The Chair of the Scientific Advisory Committee for each disease research theme is a member of the Board. Members of the Board are listed here: https://www.iddo.org/governance/iddo-board

IDDO Data Access Committee (IDDO DAC) – means the independent committee appointed to approve Data Requestor access to Data; the IDDO DAC consists of expert-led subcommittees that review applications relating to Platform disease research themes.

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

IDDO Data Platform (the Platform) – means the platform developed and maintained by IDDO and the University of Oxford on which data are collated and curated. Data are managed by a governance and ethical framework to responsibly promote the availability of data for sharing and reuse in order to generate new knowledge.

Publication – any abstracts, reports, external communication, websites, presentations or other peer-reviewed scientific publications that contain information, data or Research Results that are directly or indirectly related to the Platform Data.

Research – means the research to be performed by the Requestor as described in the Data Access Application.

Research Results – means the results of the research performed by the Requestor using the Data, including all Intellectual Property Rights, Derived Data and Enriched Data that are generated.

Data Access Secretariat – the entity responsible for management of the legal, regulatory, contractual and administrative aspects of the IDDO data access process in accordance with the governance framework of the Platform, including providing technical and administrative support to the IDDO DAC. The Data Access Secretariat works with experts across IDDO to provide advisory input on the datasets requested in the Data Access Application.

Subcommittee – the IDDO DAC sub-divisions that ally experts on specified disease research themes; the current IDDO DAC subcommittees are: [1] emerging infections and [2] malaria and neglected tropical diseases.

Theme – An area of research utilising Platform Data through collaborative study groups with the research community to address knowledge gaps and conduct research that delivers benefits to disease-affected communities.