

COVID-19 Data Platform:

Data Access Committee Terms of Reference Version: 1 October 2020

1. Date Approved and Governing Body	<p>These Terms of Reference (ToR) will be agreed by the Data Access Committee (DAC). The DAC is an independent body, chaired by a representative of TDR, the Special Programme for Training and Research in Tropical Diseases.</p> <p>Where external guidance is required by the DAC, the IDDO Board and ISARIC Senior Management Team are available for consultation.</p> <p>The DAC formally adopted these TORs on the date of their first meeting.</p>
2. Purpose	<p>The COVID-19 Data Platform (“Platform”) has been established to develop and promote research on COVID-19. The Platform fulfils this purpose through:</p> <ol style="list-style-type: none"> 1. Curation (including de-identification, standardisation and cleaning) of COVID-19 data; 2. Management of requests for access to de-identified COVID-19 datasets; 3. Promotion of scientific collaboration and equitable access to data. <p>The purpose of the Data Access Committee is to:</p> <ul style="list-style-type: none"> • 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. • Define 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. <p>In the execution of its responsibilities and decision making, the DAC will apply the principles that govern the use of the Platform, in line with the Data Access Guidelines and missions of the International Severe Acute Respiratory and emerging Infections Consortium (ISARIC) and the Infectious Diseases Data Observatory (IDDO).</p> <p>The members of the DAC will ensure 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 DAC are considered confidential until public release as set out below.</p>
3. Membership	<ul style="list-style-type: none"> • The Data Access Committee shall comprise no more than 16 members and no fewer than 6. It will be constituted from diverse representation from regions affected by the COVID-19 pandemic; 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. <p>The DAC will endeavour to avoid gender and geographical imbalances.</p>
4. Eligibility	<p>Members must agree to abide by the Conflict of interest Policy <u>and the governance framework for the Platform</u>.</p> <p>The Chair is appointed as a representative of TDR. Other members will be appointed in their personal capacity, on the basis of their individual expertise.</p>
5. Proxies	<p>Members cannot appoint a proxy.</p>

6. Membership Term	The DAC members can hold their position for 3 years, and can be re-elected for a maximum of 3 terms. Appointment to the 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 DAC can be revoked 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. 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 DAC.
9. New Members	Members will be selected through an open nomination process and decision by the Chair. Current DAC members, IDDO collaborators, ISARIC partners and the general public have equal opportunity to make nominations.
10. Chair	A Chair shall be appointed by TDR, the Special Programme for Research and Training in Tropical Diseases. 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 another 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 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 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 Platform Secretariat is comprised of staff from both ISARIC and IDDO, University of Oxford. The Secretariat will provide administrative services to the DAC. It will receive and distribute communications on its behalf, and manage and coordinate required meeting activities in accordance with the Secretariat Terms of Reference. The Secretariat will make available, where possible, summaries of DAC minutes, decisions and materials online at www.iddo.org .
13. Quorum	No business shall be transacted at any meeting of the DAC unless a quorum is present, nor any decision taken via email unless a quorum respond. A quorum is at least 6 members. The Chair shall count towards quorum.
14. Frequency of Meetings	The DAC will meet initially via videoconference to approve relevant governance documentation, with subsequent review decisions made remotely via email or other electronic means. A meeting via teleconference may be called at any time when requested by the Chair or by at least two members of the DAC upon reasonable notice to other members.
15. Operation of the Data Access Committee	The DAC may regulate its own procedures subject to the provisions of these Terms of Reference.

	<p>The 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.</p> <p>Any member is welcomed to place an item on the agenda for a DAC meeting. Advanced notice to the Secretariat is appreciated when possible.</p> <p>The Secretariat shall keep minutes of the proceedings of any meeting of the DAC and distribute minutes to all members.</p> <p>All members will receive a copy of all requests for data access.</p> <p>Collective decision-making will be enabled using a secure online system, enabling a rapid review turnaround. The DAC aim to provide responses to requests for review of data access applications within 3 business days. Applicants will be notified of the outcome of their application as soon as possible, and within 1 month.</p> <p>Each party will execute its duties in good faith.</p>
<p>16. Duties: Decision Making and Responsibilities</p>	<p>Members will be notified via email when a new application is submitted for review. Members can vote to approve, conditionally approve, reject or reconsider an application. Votes to reject or reconsider must be accompanied by a rationale. All votes and rationale will be visible to all members. Each application will require 6 votes only to determine the decision of the DAC. Voting will be terminated after the first 6 votes, except in the cases as outlined below.</p> <p>An application that receives 6 approval votes within the review period agreed by the DAC (3 business days) and no rejection or reconsideration votes will be approved.</p> <p>An application that receives more than 1 vote for rejection or reconsideration within the first 6 votes will be returned to the applicant with appropriate feedback based on the rationale given by members. The contents of the response will be decided by the Secretariat, with input and endorsement of the Chair.</p> <p>If an application receives a single vote for rejection or reconsideration within the first 6 votes:</p> <ul style="list-style-type: none"> • all members will be notified that further review is needed; • voting will remain open for members who did not already vote; • members who submitted the first 6 votes will be asked to confirm their vote - their vote can be retained or changed following the consideration of all votes and rationale submitted; • within the totality of these votes: <ul style="list-style-type: none"> ○ applications with no votes for rejection or reconsideration will be approved. ○ applications with more than 1 vote for rejection or reconsideration will be returned to the applicant with appropriate feedback based on the rationale given by members. The contents of the response will be decided by the Secretariat, with input and endorsement of the Chair. Or ○ applications with 1 vote for rejection or reconsideration will be discussed at the next DAC meeting, to be scheduled with the participation of the member who cast the vote, as soon as is practical. <p>When meeting, the DAC shall use best endeavours to take decisions by consensus (meaning all those present in the meeting agree). If consensus on any decision cannot be reached, and unless the DAC decides otherwise, its decisions shall be taken by a simple majority. Where there is no majority, the Chair shall have the casting vote.</p> <p>Each individual member has one vote.</p>

	<p>The DAC shall have the following powers and responsibilities:</p> <ul style="list-style-type: none"> • to manage and oversee all research applications to access data from the Platform including reviewing, approving, denying and requesting further details on applications in accordance with these Terms of Reference (ToR) and the Data Access Guidelines, and providing written answers to applicants; • if deemed useful by the DAC, to refer the application for external advice by a subject-area expert (selected by DAC members and approved by the Chair) to provide an opinion to inform the DAC’s decision; • to define the data sets to be released; • to provide regular input to the IDDO Board, ISARIC Management Team and Platform Secretariat on emerging issues in data access and any implications for Platform strategy and policy; • to seek advice from the Platform 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 Platform Secretariat any applications that would benefit from an evaluation by the IDDO Board or ISARIC Management Team, specifically: <ul style="list-style-type: none"> ○ 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 or ISARIC Management Team; • determine any variance in reporting requirements for those granted access to data; • proactively engage stakeholders where appropriate in the Platform.
<p>17. Principles, Ethics Approach and Accountability</p>	<p>The DAC will operate a fair, transparent, equitable, efficient, timely, effective and well-governed system to make data accessible in order to facilitate research and encourage rapid publication.</p> <p>The DAC with assistance from the Secretariat will monitor data access requests (both those accepted and rejected) and their management 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.</p>
<p>18. Interests of Data Access Committee Members</p>	<p>All members of the 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.</p> <p>The Chair of the 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 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.</p> <p>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-</p>

	associated persons, ISARIC-associated persons, the Secretariat, DAC members, previous members/representatives or associated persons will be managed in accordance with the Conflict of Interest policy and any 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 applicants of all applications made, DAC decisions (approved/rejected - with reasons), conditions on approval and recommendations on publication, all approved applications, as well as records of all 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 DAC shall keep these Terms of Reference under review. Any changes to these Terms of Reference may be made with unanimous support of DAC membership.