The Data Access Committee ("DAC") will follow these Guidelines when evaluating applications to access data held on the COVID-19 Data Platform ("data"). All approved applications require a Data Transfer Agreement signed by the Data Requestor and the platform host (University of Oxford) before the data are made accessible.

Application

Each Data Requestor will submit a Data Access Application in the form set out in Annex 1 to these Guidelines.

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 at 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.

The Platform Data Access Process

Please refer to the COVID-19 Data Access Committee Terms of Reference for the full committee procedures. Briefly:

- There is no fee or other cost for Data Requestors to access the Platform Data.
- All applications will be reviewed for completion by the Secretariat. Complete applications will be forwarded to the DAC for review.
- The DAC will respond (via the Secretariat) with their decision within 1 month from the date of receipt of a complete application.
- The DAC can decide to:
    - approve the application;
    - approve the application subject to the Data Requestor obtaining funding and/or necessary approvals;
    - ask for further clarification or amendment by the Data Requestor;
    - if the application does not meet these Guidelines, reject the application; <u>AND/OR</u>
    - send the application for advice of an independent expert in accordance with the criteria set out in the DAC Terms of Reference.
- 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 subsequent application. Disputes and/or appeals regarding the data access decisions will be managed by the IDDO Board or ISARIC Management Team at the request of the DAC Chair.
- The DAC defines the data sets to be released.

Addressing Research Priorities

Applications will be approved provided they demonstrate how the proposed analysis will address a research question with respect to improving the understanding or response to COVID-19 infection. Where appropriate, applications should make reference to published global research agendas, such as those developed by the WHO and the African Academy of Sciences, and/or demonstrate how the applications will contribute to national COVID-19 research priorities.

Where applications must be prioritized due to heavy volumes, those deemed by the DAC to have the greatest scientific value (see below) and those developed in partnership with national health authorities will have priority.

Platform Data Protection

No personal/identifiable data will be transferred or otherwise made available to Data Requestors.

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 a published global COVID-19 research agenda 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 (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 to data from the platform.

<u>Researchers</u>
Access to data is limited to Data Requestors working in a field relevant to COVID-19 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. Applicants seeking mentorship or academic support to undertake an analysis can be referred to ISARIC or IDDO to identify a collaboration.

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 Transfer Agreement.

<u>Ethics</u>
The DAC must be satisfied that there are no concerns with respect to the ethical aspects of the application. The DAC will consider public health ethics, global emergency ethics, 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 will additionally be considered.

<u>Conflict of Interest</u>
The DAC must consider any conflicts of interest declared and ensure that they do not risk compromise of the quality or integrity of the proposed use of Platform Data.

<u>Collaboration and Knowledge Sharing</u>
Effective research on COVID-19 demands strong global collaboration. The platform partners, including IDDO, ISARIC and TDR, 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, especially those that request access to data collected in low-resource settings, should provide details of how the research will involve local partners and/or bring benefit to these communities. Examples of such initiatives include:

- the application is led by or includes collaborative partnerships with the research community in a low-resource setting,
- the application develops research capacity in low-resource settings,
- the applicants are supporting an appropriate capacity building initiative in an area related to the application,
- the application has a strategy to share knowledge directly with regional/national health authorities.

Approvals

All required scientific and ethical reviews and/or approvals must be obtained before any Data are disclosed to the Data Requestor.

The Data Requestor must have the necessary legal, scientific and/or ethics approvals from their institution. Applications may be considered while approvals are in process and approved by the DAC pending confirmation of receipt.

Platform Data Transfer Agreement

Before any Data are disclosed, Data Requestors will be required to enter a standard Data Transfer Agreement with Oxford University imposing obligations on the Data Requestor that are intended to ensure compliance with the key principles underpinning the Platform.

COVID-19 Data Platform - Data Access Application Form

Please review the Data Access Guidelines and the Data Transfer 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 COVID-19 Data Platform website.

Complete all sections of this form fully and return to covid19@iddo.org.

SECTION A: RESEARCHER / RESEARCH TEAM INFORMATION	
Lead Applicant Details	
Title	
First name (given name)	
Surname (family name)	
Gender	
Position at employing organisation/ institution	
ORCID ID (https://orcid.org) **or URL to academic profile**	*(if no ORCID or URL, please attach a short academic CV)*
Email	
Employing Organisation/Institution *Institution with a remit including health, research or academic pursuit, and with legal status which includes the scope to sign the **Data Transfer Agreement.***	
Institution name	
City, Country	
Does your institution agree to execute the Data Transfer Agreement? (if your application is approved)	**YES/NO** (delete as appropriate)
Co-applicants *ALL individuals accessing the data must be listed. Any additions must be notified to the COVID-19 Data Access Committee. Add rows as necessary.*	
1. Name	
1. Position / Role in analysis	
1. Organisation/Institution	
2. Name	
2. Position / Role in analysis	
2. Organisation/Institution	
3. Name	
3. Position / Role in analysis	
3. Organisation/Institution	
Conflicts of Interest *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)*	

SECTION B: RESEARCH PLAN

Title of Proposed Research	

Is this a re-submission of a previous application to the COVID-19 DAC? If yes, provide the submission date of the previous application.	

Summary of Research in Lay Language *(suggested ~ 100 words)*

Summary of Research Objectives and Scientific Value *(suggested maximum 400 words)*

Primary and Secondary Outcome Measures *(suggested maximum 200 words)*

Proposed Methodology and Statistical Analysis Plan *(suggested maximum 400 words)*

Ethics *(suggested maximum 300 words)*
Provide details of any ethical considerations relating to the research proposal.
Additionally, list any approvals required by your institution to undertake this work, list reference numbers of any approved proposals, or explain why no approvals are required.

Publication and Dissemination Plan *(suggested maximum 300 words)*
Provide details of plans for authorship/acknowledgement of data contributors.
Provide details of timelines for publication and dissemination of research findings.

Research Priorities Addressed (*suggested maximum 300 words)*
Provide details of how this research aligns with nationally or internationally set research priorities.

Collaboration and Knowledge Sharing *(suggested maximum 300 words)*
Provide details of how this research will collaborate, support and/or share knowledge with appropriate partners. The platform is particularly interested in research that builds capacity in low-resource settings.

Funding *(suggested maximum 100 words)*
Provide details of how this research will be funded/resourced. Please name the source of funding.

Scientific Review *(suggested maximum 200 words)*
If the project has been scientifically reviewed, please provide details. This could be by your institution, a funder/donor or review committee.

SECTION C: DATA

Data Variables
*Provide a list of the **data variables** required to achieve the research objectives.*
Note: Please go to www.iddo.cognitive.city to explore the interactive COVID-19 data inventory and to identify the variables, populations and data volumes required for your analysis. You can select the data variables from this inventory and copy it to this section.