ICODA Review Processes

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Introduction

The International COVID-19 Data Alliance (ICODA) has committed to meet the 'Five Safes' framework (see Box 1) to foster responsible and trustworthy uses of data. To ensure 'Safe People', researchers need to be accredited before they can access the ICODA Workbench, a trusted research environment from within which researchers can perform their work. To ensure 'Safe Projects', research proposals will be reviewed to ensure a valid research purpose with a defined public benefit.

Box 1: The Five Safes

ICODA's data governance policies will be based on the 'Five Safes' framework[1]:

- ***Safe projects:*** Is the use of data appropriate?
- ***Safe data:*** is the risk of disclosure in the data minimised?
- ***Safe people:*** can users be trusted to use the data in an appropriate manner?
- ***Safe settings:*** can data be accessed in a Trusted Research Environment?
- ***Safe outputs:*** are there disclosure risks from reported results?

https://www.ons.gov.uk/aboutus/whatwedo/statistics/requestingstatistics/approvedresearcherscheme#the-five-safes; https://www.ukdataservice.ac.uk/manage-data/legal-ethical/access-control/five-safes

Key Principles

The process must:

- be proportionate.
- meet the 'five safes' framework and help build a trustworthy approach.
- be light-touch and streamlined to allow access to be approved rapidly.
- be scalable.
- be equally accessible for researchers anywhere in the world.
- Where multiple datasets are involved, every effort must be made to avoid duplicating review processes.
- For security and to handle changes of circumstance, access is timebound and should be subject to review at regular intervals.

Data custodians will be given a choice of using their own existing review processes or delegating to ICODA's mechanism. This document sets out the approach that will be taken:

A. if the data custodian decides to delegate the review processes to ICODA.
B. where open access datasets are made available through the Workbench.
C. where data is provided to SAIL, ICODA's databank partner.

A. ICODA's Review processes

Figure 1: Review Processes

Figure 1 shows the processes that ICODA will undertake in order to meet the 'safe people' and 'safe projects' requirements, and ensure appropriate use of data through the Workbench. The processes to select and approve a Driver Project, and to review whether data has been collected appropriately before it can be onboarded, are addressed separately here. All Driver Projects must have the potential to have direct impact to address the COVID-19 pandemic and provide patient benefit.

Once data is available for access, a researcher can search for data through the ICODA Gateway. The Gateway includes a number of functions:

- search engine to allow researchers to discover data
- data Access Request form for researchers to apply for data
- automated back-end processes to support the researcher accreditation and review of research proposal processes.

The next two sections set out the process for researcher accreditation and review of project proposal. The two processes can happen in parallel rather than sequentially. However, we have illustrated them as separate reviews because, in future, an accredited researcher might apply to access data for a second research project. In such a case, the researcher accreditation would not need to be repeated, only the project proposal would be reviewed.

A.1 Accreditation of Researchers

In order to ensure access is restricted to 'safe people', ICODA has introduced a process to accredit researchers. This will help ensure users can be trusted to use data in an appropriate manner, giving confidence to data contributors that data will be used responsibly, and enabling high quality research to be conducted using data in the Workbench.

The process of accrediting researchers is as follows:

1. Researcher completes registration information

The researcher needs to provide the following information through the application form:

- Full name
- Job Title
- Institutional affiliation
- Organisation details
- Telephone
- Email
- ORCID
- Role on research team
- Evidence of (individual or team's) expertise and experience relevant to delivering the project. (*This should include education, professional qualifications and memberships that are relevant to the research, including any up to date Information Governance training. For example, in the UK this might be evidence of completing the ONS Safe User of Research data Environments (SURE) Training course, or the MRC's regulatory support centre confidentiality e-learning. For researchers in low- and middle-income countries, The Global Health Network also offer a certified data sharing course. Within a team, we would expect to see at least one qualified statistician, or someone with equivalent experience.)*

Researchers are asked to include the name and job title of each member of the team who will have access to data, and to specify the principal investigator, statistician and study coordinator.

For Researcher Accreditation institution/organisation email addresses are preferable, but we realise not always practical for all team members. An institution/organisation email address is

required for the Principal Investigator/s, and preferable for all researchers accessing the Workbench - even if this is not the email address you will use to log in to the Workbench or day-to-day communication with the ICODA team.

The Principal Investigator oversees and is responsible for the actions of researchers undertaking research in the Workbench, including that they are bona fide researchers and will comply with ICODA's

2. Review by ICODA research manager

The research manager (a member of the ICODA team) will undertake a light-touch check of researcher credentials, using the following criteria:

- All the requested information has been provided
- The researcher is affiliated to a legitimate organisation conducting research (verified via institutional email address, institutional webpage profile or publication record)
- The researcher is a bona fide researcher (see Box 2)
- The researcher has the professional qualifications and experience to work with health data.

Across a team, we would expect to see at least one qualified statistician, or someone with equivalent experience.
If any of the requested fields have not been completed, or if further details are required, the research manager will contact the applying researcher for additional information. Once full details have been provided, the research manager will make an accreditation decision to the best of their judgement, but may also seek a second opinion from another member of the ICODA team for complex cases.

Box 2: What is a bona fide researcher?

The term bona fide researcher is often used but rarely defined. We use the definition adopted by the UK Medical Research Council in its Policy and Guidance on Sharing of Research Data from Population and Patient Studies.

A **bona fide researcher** is a person with
• the professional expertise and experience to conduct bona fide research and
• a formal relationship with a bona fide research organisation that requires compliance with appropriate research governance and management systems.
Bona fide research can be considered to be as follows:
• An intention to generate new knowledge and understanding using rigorous scientific methods. (This includes discovery research, development and validation of methodology and technology, validating and challenging previous findings, and pilot research). And…
• An intention to publish the research findings and share the derived data in the scientific community, without restrictions and with minimal delay, for wider scientific and eventual public benefit. (Recognised constraints include a short prepublication delay to ensure proper management of intellectual property). And…
• The intended activities are not inconsistent with legal and ethical requirements or widely recognised good research practice.

A **bona fide research organisation** is one that has the capability to lead or participate in high quality, ethical research. It will have a public commitment to adhere to recognised research and information governance good practice. (It is not a requirement that such research is the primary business of that organisation, or that all of the research undertaken by that organisation is published. Nor is it a requirement that the organisation be publicly funded.)

3. Decision and notification

There are two possible outcomes:

- the researcher is accredited
- the researcher's application is rejected.

The researcher is notified of the decision by email, including the reason for rejection (where relevant). The accreditation decision is recorded in the Researcher Accreditation Decisions log (kept confidentially). Initially this will be held in a password-protected spreadsheet but it will evolve to be within the ICODA Gateway.

Future developments to researcher accreditation process

The intention, as ICODA becomes more established, is to move towards using the GA4GH passport standard, to ensure interoperability with other systems. The 'Passport' provides a way for users to digitally identify themselves across different systems. 'Visas' are used to demonstrate permissions and access qualifications. The standard is interoperable, with different data platforms adding visas to the same passport after authorisation.

A.2 Review of research proposals

The second requirement of the 'Five Safes' framework is that of 'Safe Projects'. Proposals need to be reviewed to ensure the use of the data is appropriate, and that the project has a valid research purpose with a defined public benefit.

Initially, research in the Workbench will be part of a Driver Project. The ICODA Executive leadership team (ELT) will have given high-level approval of the Driver Project, but there may be specific research questions within a Driver Project that need individual review. During this initial phase, ICODA will set up a light touch process, and use the opportunity to learn what will be needed in the longer-term and to test processes.

The process of reviewing research proposals is as follows:

1. Researcher provides project information

The researcher provides basic information about the proposed project as part of the Gateway application. The fields collected are:

- Title of project
- Lay summary of project
  (*This should be written in plain English and provide a high-level overview of the research project, including a description of the anticipated public health benefit. Max 500 words*.)
- The project aims, objectives and rationale
- The methodology and statistical analysis plan
  (*To include a description of study hypothesis, primary outcome measures, statistical methodology and planned subgroup analysis*)
- Details of the data requested
- Whether datasets will be linked to any additional data
- Expected duration of the research
- Publication and dissemination plans

2. Internal review

The proposals will initially be triaged by the research manager. Those that are straightforward will be reviewed in-house, by the Driver Project lead, the Chair of the Statistical Expert Group and a clinician, as required.
More complex proposals would be sent to external independent review.

Where necessary, the researcher may need to be contacted to provide further information or clarification.

The review will be light-touch, and based on the following criteria:

- Does the research question have scientific merit?
- Could it have patient and/or public benefit?
- Is the statistical analysis plan appropriate to answer research question/s?
- Would data access facilitate high quality research?
- Is the relevant data available? Can it answer the question proposed?
- Will participant privacy be protected?

3. External Independent Review

Where necessary, if the proposal is more complex, it will be sent for external review by two or more independent expert reviewers, identified from an informal review panel. For Driver Project 1, which involves summary-level data, this will be an informal panel of expert reviewers including statisticians and clinicians. These reviewers will consider the same criteria listed above. At least two reviews will be required. The final decision will remain the responsibility of the Driver Project lead.

In future, ICODA has committed to formally set up an Expert Review Panel (see below).

4. Decision and notification

There are three possible outcomes:

- the proposal is approved
- the proposal is rejected
- the proposal is returned to the applicant with suggestions for changes that need to be made before it can be approved.

The researcher is notified of the decision, including the reason for rejection (where relevant). The decision is recorded, and metrics kept on approvals and rejections. This record will initially be kept on a spreadsheet, but over time the ICODA Gateway will evolve to allow a log of decisions to be kept in a useable form.

Reasons for rejection, which will be recorded, might include:

- Data not available to access via the Workbench
- Research proposal does not meet the informed consent requirements for that dataset
- Research proposal requires identifiable patient data or there is a risk to participant privacy
- The proposal is not in the public interest

5. Appeals process

A comparative analysis found that many Data Access Committees do not have a formal appeals procedure as it was deemed unnecessary: there are often few or no refusals of access, and no

experience of dissatisfaction with the DAC decisions.[1] However, given ICODA is still in a learning phase, the Ethics Advisory Council has suggested that we should offer an appeals process initially. Any appeals will be escalated to the ICODA Executive Leadership Team (ELT).

6. Transparency reporting

ICODA is committed to transparency across all its activities, and so will provide information about all research projects that have been approved to take place in the Workbench.

For projects that have been approved, we will publish the researcher's name, organisational affiliation, project title and lay project summary on the ICODA website: https://icoda-research.org/transparency-reporting/.

For projects that are not approved, we will publish the reasons for rejection, using agreed categories.

Future developments to the project review process

We will keep this process, and the reporting arrangements, under review, and will also seek input from the Public Involvement Expert Group once it is in place.

In the longer-term, data will be available for researchers to access through the ICODA Workbench for any research project, not only Driver Projects. At this stage, it will be important for ICODA to have an External Review Panel in place, to review and make decisions about research requests. The ICODA team will work with the Ethics Advisory Council to scope and progress plans to establish an external Expert Review Panel.

[1] EAGDA, Governance of data access (2017)

B. Review processes for open datasets

ICODA is also making some open datasets available through the Workbench, ie datasets that are also available elsewhere with no restrictions. Given these datasets are already freely available, it will be important not to introduce additional hurdles. However, we do need to ensure that researchers accessing the Workbench are accredited, and that use of ICODA compute and analysis resources is for public benefit. We also need to ensure that any research and outputs resulting from an open dataset adhere to relevant licensing requirements, which differs by dataset.

The ICODA ELT has therefore agreed the following approach to ensure proportionate review:

- Open dataset only
  If a researcher applies to access only an open dataset, they will still complete the application form on the Gateway, but will only need to complete information about the researchers and the project title. They will then need to be accredited as a researcher, and there will be a light touch, internal check of only the research question to ensure that there is public benefit.

- Open dataset together with other datasets accessible through the Workbench
  If a researcher applies for access to open data and existing ICODA dataset/s, the standard review process will apply. Researchers will need to be accredited and the research proposal approved.

In both cases, the researcher onboarding process will also include a reminder of applicable open dataset license terms governing use, outputs and attribution.

C. Review processes where data is transferred to SAIL databank

ICODA has formed a strategic partnership with SAIL to provide a databank and, for some projects, data will be contributed directly to SAIL. SAIL already has its own review processes in place, including an Information Governance Review Panel (IGRP).

In order to avoid duplication of review, we have agreed the following approach with SAIL:

- Where data does not leave SAIL, and is accessed from the Workbench via federated access, SAIL will retain control of all review processes. This will use SAIL's IGRP. The processes are set out here.

- Where data is transferred from SAIL to the Workbench, the review will be undertaken using ICODA's processes.