

ICODA Review processes

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Summary for external circulation

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' framework¹:

- **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.

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. All Driver Projects must have the potential to have direct impact to address the COVID-19 pandemic and provide patient benefit.

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:



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.

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.

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.)

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:



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

Review of proposals

The review will be 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?

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

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). Any appeals will be escalated to the ICODA Executive Leadership Team (ELT).

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.