Ethics and Governance Framework

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Summary and overview

The International COVID-19 Data Alliance (ICODA), convened by Health Data Research UK (HDR UK), aims to support researchers to access health data from around the world by helping to overcome some of the challenges of data sharing. This will only be possible if ICODA can inspire confidence among the public, researchers and stakeholders by demonstrating trustworthiness. This Ethics and Governance Framework (the Framework) is intended as a first step, setting out the principles that will guide ICODA's operations.

The Framework has been developed in consultation with ICODA's Ethics Advisory Council. It draws on existing national and international best practice frameworks and guidance, including the Principles of Data Sharing in Public Health Emergencies developed by Glopid-R[1] and the CARE Principles of Indigenous Data Governance.[2] The aim is for ICODA to support research that is ethical, efficient and equitable.[3]

The Framework sets out five high-level principles that will underpin all ICODA's activities. For each principle, it then defines in more detail the procedural and practical approach ICODA will adopt in order to meet the principles and deliver best practice.[4]

The Framework sets out the direction of travel for ICODA. We recognise that, in some instances, it will take time to achieve the ultimate ambition to unite health data. Where this is the case, we have set out what we will deliver initially and the steps that we intend to take in order to reach the end goal, often in partnership with others. In such a complex landscape, we understand the need to share learning and to work in collaborative partnerships if we are to change attitudes towards data sharing and demonstrate trustworthiness. We will be transparent about our progress and any challenges we face.

As we embark on this journey, the Ethics Advisory Council will monitor how ICODA meets its commitments, provide advice on ways to achieve the goals, and act as an independent guardian of this Framework. We will keep this Framework under review as ICODA develops, and share learning as we progress.

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[1] The Global Research Collaboration for Infectious Disease Preparedness (2018) https://www.glopid-r.org/wp-content/uploads/2018/06/glopid-r-principles-of-data-sharing-in-public-health-emergencies.pdf

[2] CARE Principles of Indigenous Data Governance — Global Indigenous Data Alliance (gida-global.org)

[3] Public Health Data Funders Forum (2009) Sharing research data to improve public health: full joint statement by funders of health research

[4] This approach builds on the framework proposed by Xafis, V., Schaefer, G.O., Labude, M.K. et al, in their Ethics Framework for Big Data in Health and Research. Xafis, V., Schaefer, G.O., Labude, M.K. et al. An Ethics Framework for Big Data in Health and Research. ABR **11**, 227–254 (2019). https://doi.org/10.1007/s41649-019-00099-x

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Box 1:   ICODA's Principles

ICODA asks our Researchers and Partners to subscribe to the following Principles

- Deliver **public benefit** through **responsible** use of data
- Foster **equity** in developing a global approach
- **Respect** the patients and research participants who contribute data
- **Protect privacy** through commitment to the Five Safes framework
- Be **inclusive** and **collaborative**
- Be **transparent** across all activities
- **Recognize the contribution** of data generators
- Drive **innovation** to develop an effective data sharing ecosystem.

Across all its activities, ICODA will seek to:

1. **Deliver patient benefit**
   - take a research-led approach to use data more effectively
   - deliver FAIR technical capability to allow efficient reuse of data
   - support high-quality robust research
   - promote the reporting of results.

2. **Foster equity**
   - support researchers from low and middle income countries to engage with parity
   - recognise the contribution of data generators
   - be inclusive and collaborative.

3. **Respect the patients and research participants who contribute data**
   - respect the data sharing preferences of patients and research participants
   - embed community, public and patient involvement and engagement.

4. **Protect privacy**
   - commit to the Five Safes Framework[5]
   - ensure robust data security
   - provide proportionate mechanisms to govern access to data.

5. **Provide responsible stewardship**
   - be transparent across all our activities
   - deliver accountable governance
   - move towards a new model of independent and trustworthy data stewardship.

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[5] UK Data Service

Ethics and Governance Framework

1. Deliver patient and public benefit

ICODA's overarching aim is to support researchers to use data more effectively, in order to accelerate discoveries and address the COVID-19 pandemic and future global health challenges. By enabling access to multiple research data sets for secondary analysis, ICODA will generate new evidence and support faster progress to improve health.

Building on best practice, ICODA will seek to:

- **Take a research-led approach**
  ICODA will focus initially on delivering demonstrator Driver Projects, including those identified through the Grand Challenge ICODA initiative, that are designed to bring together different datasets to tackle a specific priority question. All research conducted within the ICODA Workbench must have a valid research purpose with defined public benefit, it must have scientific merit and the potential for patient impact. Proportionate governance (see Section 4 below) will be designed to maximise benefits while minimising any harms of reuse of data.

- **Deliver a FAIR technical capability to allow efficient reuse of data**
  To harness the power of data, and ensure that resources are used efficiently, there is increasing recognition that data should be FAIR – findable, accessible, interoperable and reusable.[6] The COVID-19 pandemic has emphasised the need to make better use of data, and to have a sustainable infrastructure in place. ICODA will deliver a FAIR technical capability, so that secondary analysis of data can be timely and innovative. We will work with others to reduce complexity and streamline processes, so that researchers can access data from multiple sources as quickly as possible. ICODA will:
  - work with the HDR Innovation Gateway and other partners to improve the discoverability of data through sharing of high-quality metadata
  - provide a Trusted Research Environment for analysis through the ICODA Workbench[7]
  - provide an agile and scalable infrastructure, with an emphasis on pioneering federated approaches to reduce the movement of data.

- **Support high-quality robust science**
  ICODA aims to enable robust, reproducible science, so that the research provides results that can be translated effectively into policy and practice. We will deliver guidance, tools and training to facilitate high quality data analysis to be conducted within the Workbench, and to take into account the context in which data was originally produced.[8] Good data science also

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[6] FAIR Principles - GO FAIR (go-fair.org); The FAIR Guiding Principles for scientific data management and stewardship (2016) Science Data
[7] https://ukhealthdata.org/projects/aligning-approach-to-trusted-research-environments/
[8] GLOPID-R, Principles of data sharing in public health emergencies (2018)

depends on high quality data. We are exploring ways for ICODA to provide support where needed to help ensure data is curated to meet appropriate standards. For example, ICODA will partner with The Global Health Network to help share best practice to support and enable the generation and curation high quality data. Over time, we will also engage and partner with key stakeholders to explore how to improve the harmonisation of data standards.

- **Promote the reporting of results**
  The results of research, including negative results, must be widely shared as rapidly as possible to contribute to the broader knowledge base, to learn more quickly from each other's research, and to help ensure the findings have a beneficial impact on global health. ICODA's publication policy requires authors publishing the outputs of work using data accessed through the ICODA workbench to select publishing routes that enable the work to be available immediately in an open access form.

2. Foster equity

We recognise the lack of equity in health research. Too often, there is limited opportunity, resource or capacity for researchers in low and middle-income countries (LMIC) to analyse data to answer priority questions, and there are longstanding concerns that data sharing activities are generally centred in and benefit the Global North. To address these challenges, ICODA will adopt a global approach, working to enable 'fair trade not free trade'.[9]

Building on best practice, ICODA will seek to:

- **Support researchers from LMICs to engage with parity**
  Our aim is to strengthen capability by providing support and guidance, so that those in the global South can benefit from data collected in the global North as well as vice versa. We will work in partnership with The Global Health Network, which has a track record in knowledge sharing and capacity development, and foster local leadership and networks. The ICODA Workbench and review processes are being designed with the intention that they are accessible for researchers anywhere in the world.

- **Recognise the contribution of data generators**
  It is important to recognise the role of everyone who has contributed to research. ICODA's attribution policy requires all publications from research using data accessed through the ICODA Workbench to credit the data generators, patients and trial participants, and funders. This is intended to help give confidence to those who collect data that their effort will be recognised. Special care should be taken to include investigators located at institutions in LMICs that were involved in the original data generation. The different contributions of

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[9] Pisani E, Whitworth J, Zaba B and Abou-Zahr C. Time for fair trade in research data. The Lancet 375, p703-705

members of a research team should also be acknowledged, using CASRAI's Contributor Roles Taxonomy (CRediT) system.[10]

- **Be inclusive and collaborative**
  Building research communities across different cultural contexts takes time and effort, but an emphasis on diversity is important to enable equitable access for all. ICODA will work with an inclusive alliance of global partners, building networks and communities of practice to learn from each other and share best practice. The most effective way to address the challenges of data sharing will be to work collaboratively and ensure a coordinated approach.

3. Respect the patients and participants who contribute data

It is essential to recognise and respect the individual data sharing preferences of patients and research participants as far as possible. The CARE guidelines emphasise the importance of giving participants "authority to control", including providing dignity to communities. As identified in the Consensus Statement on Public Involvement and Engagement with Data-Intensive Health Research, there is a particular challenge with data reuse because the researchers analysing the data will typically have no contact with those from whom data are derived.[11] It is unlikely that individuals will have given explicit consent for a specific reuse. It is therefore increasingly important to explore ethically acceptable alternatives so that an intended reuse of data is acceptable, transparent, and reflects public values and interests. Public involvement and engagement have a key role 'to bridge the gap between data scientists and the people to whom the data relates'. [12]

Building on best practice, ICODA will seek to:

- **Recognise the data sharing preferences of participants**
  In order to respect the preferences of participants, data from clinical trials will only be reused if the initial consent sets appropriate expectations. ICODA will rely on the data contributor to check that the consent given allows reuse of the data, and to flag any restrictions that may be relevant. We recognise the importance of ensuring that data is collected in an ethical way, and will continue to consider what steps ICODA might realistically take to undertake due diligence when accepting data onto the ICODA Workbench or facilitating federated analysis. We recognise that the situation may be more complicated with real world evidence, but there must be an appropriate way to respect and protect patients.

- **Embed community, public and patient involvement and engagement**
  Ensuring that the public and patient voice is included in ICODA's governance will be an important part of building confidence in ICODA's decision-making processes. We recognise

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[10] CRediT - Contributor Roles Taxonomy (casrai.org)

[11] Aitken, M. et al "Consensus Statement on Public Involvement and Engagement with Data-Intensive Health Research", *International Journal of Population Data Science*, 4(1). doi: 10.23889/ijpds.v4i1.586.

[12] Aitken, M. et al "Consensus Statement on Public Involvement and Engagement with Data-Intensive Health Research", *International Journal of Population Data Science*, 4(1). doi: 10.23889/ijpds.v4i1.586.

the difficulty of embedding engagement at a global scale, particularly given the diversity of approaches in different countries. We are therefore taking advice on the development of a strategy, including holding a Workshop in November 2020 and a breakout session at the ICODA Forum meeting. We have developed an initial strategy for community engagement and public and patient involvement, which we will continue to iterate. The strategy includes four key pillars:

- o embed public and patient voices in ICODA's governance, including establishing a dedicated Public and Patient Voices Expert Group
- o work in partnership with expert groups in community engagement and patient and public involvement
- o ensure transparency throughout ICODA's work and communications, emphasising inclusivity and accessibility, with a particular focus on explaining how data is used and how it is kept secure.
- o focus initially on involvement and engagement for Driver Projects, to allow the work to be more tangible and to learn lessons about the practicalities of engagement.

4. Protect privacy

Respecting the privacy of participants, reducing the risk of harm from uses of data and preventing data misuse are of paramount importance. ICODA must adopt a robust approach to check that uses of data are responsible and transparent, with clear mechanisms to control access to information about individuals and meet local data protection requirements.

Building on best practice, ICODA will seek to:

- **Commit to the Five Safes Framework**
  The Five Safes Framework, first defined by the UK Office of National Statistics, helps ensure responsible use of data by focusing on five aspects: safe people, safe projects, safe data, safe settings, and safe outputs.[13] Table 1 sets out the measures that ICODA will put in place to meet the Five Safes Framework.

- **Ensure robust data security**
  Robust IT and security measures must be in place to reduce the risk of data misuse. ICODA will ensure that the Workbench conforms to relevant security standards, including audit and processes to identify and respond to any data breaches. The Trusted Research Environment of the Workbench provides a 'safe setting'. We will also seek equivalent guarantees from partner Data Banks.

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[13] UK Data Service

Table 1: ICODA's commitment to the Five Safes Framework

	Key principle	ICODA controls
Safe people	Users must be trusted to use the data in an appropriate manner	Accreditation process for review and registration of users Researchers need to sign legally binding terms of use before they can access data
Safe projects	The use of the data must be appropriate	Review process to assess and approve research proposals Local level check that the consents are appropriate for reuse
Safe data	The disclosure risk in the data itself must be minimised	Data must be de-identified as far as possible before it is transferred to the Workbench, in order to reduce any potential risk of identification. ICODA will make support available to help with de-identification where necessary. Only data relevant to the specific analysis should be shared. A clear policy on data retention will set out how long data will be kept for.
Safe settings	Data can only be accessed within a 'Trusted Research Environment' (TRE)[14]	The ICODA Workbench is a TRE, with robust information security and project-level audit trail. Role based access controls are in place to prevent unauthorised use Checks are made on tools and data before import into Workbench
Safe outputs	There must be no disclosure risk from reported results	Output checks must be carried out before any results are exported, with a process agreed for each research project.

- **Provide proportionate mechanisms to govern access to data**
  Data contributors will be given the choice whether to use their own review mechanism, or to delegate to ICODA's central mechanism. Where data contributors choose to use their own review, ICODA will seek reassurance that the approach is appropriate, but will not otherwise duplicate the review. Where data contributors choose to delegate to a central mechanism, ICODA has established a proportionate review mechanism, to accredit researchers and approve individual research projects. This process should consider the risk of any

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[14] For further details about the requirements of a Trusted Research Environment, see: https://ukhealthdata.org/projects/aligning-approach-to-trusted-research-environments/

unintended harms from the use of data, for example the potential of discrimination. All decisions will be reported transparently. We expect ICODA will also need to establish an independent Expert Review Panel to support the review process. We will work with the Ethics Advisory Council to make sure this is done appropriately and publish further information on ICODA's website in the near future.

5. Provide responsible stewardship

Embedding responsible data stewardship is crucial to demonstrate trustworthiness and inspire confidence among all stakeholders, researchers, patients and the public in how data is used. Good data stewardship should support responsible uses of data, both checking that data is used safely and with appropriate protection while also facilitating its optimal use for patient benefit.

Building on best practice, ICODA will seek to:

- **Be transparent across all activities**
  ICODA has committed to be open and transparent about its governance, operations and ways of working. This will include communicating in a clear and accessible way about how data is used and how it is kept secure. We will provide details about all research projects that have been approved to take place in the ICODA Workbench, including information about the researchers involved, and information about requests to access data that have not been allowed. We will also share news about the outputs generated using data accessed through the Workbench.

- **Deliver accountable governance**
  ICODA will have transparent and robust governance processes, with the aim to promote the public interest, and will be open to scrutiny. Details of the governance bodies, including membership, are available on the website, and we will publish minutes of the Advisory Councils in a timely manner. The public and patient expert group will also have a role to scrutinise ICODA's decision-making processes.

- **Move towards a new model of data stewardship**
  Data stewardship encompasses the responsible use and management of data. It is increasingly used as a broad term which reflects governance – the structural conditions that enable data to be used in trustworthy ways – rather than a narrowly compliance-based approach.[15] In order to reduce complexity, and to streamline processes for requesting access to and using data on an international scale, ICODA is exploring whether a new approach involving a trusted third party to provide data stewardship would be helpful. We will work with partners to explore and develop an appropriate legal entity, with regional leadership and appropriate ethical checks, as a first step to provide trustworthy data stewardship.

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[15] Exploring legal mechanisms for data stewardship | Ada Lovelace Institute