Ethics Advisory Council

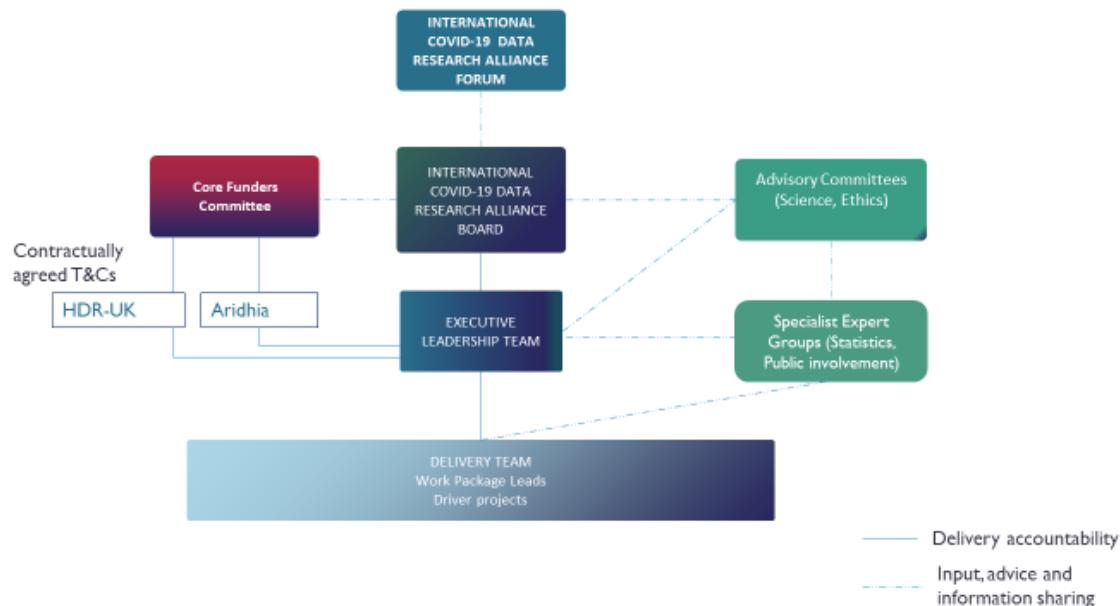## *Terms of Reference*

February 2021

Contents

International COVID-19 Data Alliance

COVID-19 represents an unprecedented public health, social, medical and economic crisis. There is an urgent need to enable access to data that can be linked with other data in a safe and secure way, for the world's research community to answer key questions. Those answers are urgently needed to address the pandemic, to save people's lives now and in the future. The International COVID-19 Data Alliance (ICODA) will provide a co-ordinated international response to enable researchers to access global data to derive rapid insights about COVID-19. It will build a trustworthy international data infrastructure and workbench, allowing analytical tools to be bought to shared data sets in a secure way to facilitate collaborative research.

ICODA is an independent consortium of leading life science, philanthropic and research organisations uniting to respond to the COVID-19 global pandemic. It is funded by the Gates Foundation and the Therapeutic Accelerator, with delivery coordinated by Health Data Research UK.

In order to build a trustworthy partnership, it will be important to ensure robust and transparent governance processes, with clear lines of accountability. ICODA must be open to scrutiny across all its activities.

1. Governance structure

This document sets out the role and remit for the entities set out above, with a particular focus on the Ethics Advisory Council.

2. Overview of governance

A. Oversight and decision making bodies

Title	Core Funders Committee	ICODA Forum	ICODA Board	Executive Leadership Team
Role	Oversees investment in ICODA	To bring Partners together	Informing high-level strategy	Executive decision-making
Remit	Maintain alignment to Therapeutics Accelerator Strategy Oversight of investment, ensure expenditure is in line with grant terms Consider role of Alliance in context of wider efforts to tackle Covid-19 and support Alliance to achieve goals	Provide input into strategy and priorities, share ideas and contribute to projects Ensure stakeholder alignment and community building Information sharing, discuss challenges and celebrate success	Providing advice to the Executive Leadership Team Supports international reach and acts as a global advocate Receives advice from Advisory Committees Provides advice on portfolio of Driver Projects	Ensure integration of Alliance, Workbench, research projects and gateway Oversight of delivery of Driver Projects and Work Packages Manage core operational decisions Accountable for delivery to the funders and Alliance partners
Frequency	Three times a year	Twice a year (plus additional workshops and targeted meetings)	Quarterly	Weekly

B. Specialist advice and expertise

	ADVISORY COUNCILS Provide high-level advice to inform strategic direction		SPECIALIST EXPERT GROUPS Provide expert advice on a day-to-day basis	
	Scientific and Strategic Advisory Council	**ETHICS ADVISORY COUNCIL**	**Statistics Expert Group**	**Public and Patient Involvement Expert Group**
Remit	Provides advice on: Identifying opportunities to help tackle the Covid-19 pandemic. Driver projects and prioritisation of research questions Ensuring the Alliance is truly international Ensuring the Alliance can deliver scientific impact	Provides advice on: Ethical and information governance issues that arise during the development and operation of the Alliance The Alliance's public involvement and engagement strategy The development of ICODA's Ethics Framework and how ICODA meets commitments set out in the Framework		To be defined in consultation with public / patient representatives, and with advice from Ethics Advisory Committee on community engagement
Frequency	3-4 times a year	3-4 times a year	Monthly	Monthly

3. Ethics Advisory Council – role and remit

Role

The Ethics Advisory Council (EAC) will provide high level advice to the Board on ethical and information governance[1] issues that arise during the development and operation of the Alliance, helping to guide ICODA to develop a trustworthy and transparent approach.

In order to build confidence among the public, researchers and all stakeholders, ICODA will develop a robust and transparent Ethics and Governance Framework, setting out the high-level principles that will guide its operations. This Framework will be developed by the central ICODA team in collaboration with Alliance partners. The EAC will provide advice on the development of the Framework, approve it and act as an independent guardian of the Framework.

The EAC will give particular emphasis to providing guidance that reflects the diversity of countries involved. It will provide advice to ICODA on the adoption of good practice to encourage fairness between researchers in different countries, particularly for those in low and middle income countries, and equitable distribution of the benefits of research. The EAC will also focus on ICODA's commitment to public and community engagement and involvement, providing advice to help ICODA adopt approaches that are appropriate within different cultural contexts.

The EAC's role will be advisory only. It is an independent body within the Alliance governing structure, that provides advice, support and challenge to the Alliance Board, and acts as a critical friend.

Remit

- To provide expert advice to the Alliance Board on ethical issues that arise during the development and operation of the Covid-19 Research Data Alliance, and the use of the workbench, including:
  - to assist in identifying relevant ethical issues,
  - providing advice, guidance and recommendations on relevant ethical issues, and
  - reviewing and providing advice on the development of new policies.

- To provide input and advice on the development the Alliance's Ethics and Governance Framework, drawing on existing national and international best practice, and to approve the Framework and act as an independent guardian for it.

- To provide advice on the Alliance's engagement strategy, taking into account the different cultural contexts where data will be generated and used.

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[1] We use Information Governance to relate to the handling of data for research purposes, rather than to cover corporate aspects of how ICODA / HDR UK handles personal data for operational purposes.

- To review and provide advice on specific questions that the Board or Scientific & Strategic Advisory Council ask the EAC to consider.

In order to ensure that there is no overlap with the working of other internal and external committees, matters that fall outside the remit of the EAC are as follows:

- The EAC is not responsible for ensuring that the Alliance's policies and activities conform to the relevant legal standards.

- The EAC is not responsible for operational activities such as the review of individual access applications, which will be considered by the relevant access mechanisms. The only exceptions are if the access committees ask the EAC for a view, or if the EAC considers that a clear and important ethical or legal issue is at stake in relation to a particular application.

Membership

1. The EAC will build on the expertise of the HDR UK International Council of Reference (ICR), an existing part of HDR UK governance, but will have a broader remit and membership, in line with the broader role of ICODA.

2. The EAC shall have at least 6 members, drawn from a diversity of backgrounds, experience and expertise. Its members should have expertise in the following areas:
   - Governance
   - Bioethics and data ethics
   - Privacy protection, including legal compliance
   - Data Science
   - Public health
   - Representing patient and public interests, with an understanding of community engagement.

3. The EAC must be truly international, and reflect a range of cultural contexts, including representation from low and middle income countries.

4. Members will serve for three years, with the possibility through mutual agreement to serve for a second term. Members cannot serve for more than two terms.

5. The EAC is independent of ICODA and its constituent members, in both its affiliations and its actions. Members will declare any Conflicts of Interest, and will be expected to respect the confidentiality of any sensitive information shared as part of discharging EAC's remit.

Ways of working

1. **Frequency of meetings:** The EAC will meet three or four times a year (although may need to meet more regularly initially). Ad hoc meetings may also be called. Meetings are expected to be virtual.

2. For specific topic areas, members of the EAC may need to liaise directly with other members of the Alliance board and / or delivery sub-groups. This will be carefully managed to ensure the time demands on EAC members are minimised.

3. **Notice of each meeting:** Meetings of the EAC shall be called by the Chair of the EAC in consultation with the Secretariat. Unless otherwise agreed, notice of each meeting confirming the venue, time and date, together with an agenda of items to be discussed and supporting papers, shall be sent to each member of the EAC no later than 5 working days before the date of the meeting.

4. **Secretariat:** The Secretariat function shall be provided in the first place by HDR-UK (central International Alliance team). The Alliance will need to build appropriate internal resource to support the EAC and associated operational functions.

5. **Attendance by Alliance staff:** The Alliance Director will attend meetings. Where appropriate, it is anticipated that other senior leaders from the Alliance and its delivery sub-groups may also be invited to attend sessions of the EAC, in consultation with the Chair of the EAC.

6. **Other attendees:** EAC may invite additional experts to join specific discussions or meetings to provide advice on specific areas of technical expertise if required.

7. **Resources:** The EAC will have access to sufficient resources in order to carry out its duties, including the ability to commission external advice on relevant ethics or legal issues if appropriate and access to the Secretariat for assistance as required.

8. **Other matters:**
   - Members will be offered an honorarium and reimbursed for all reasonable costs for attending meetings.
   - The EAC is committed to transparency of communication in the discharge of all its functions.
   - The EAC's role will be advisory only. It does not have a regulatory function, executive powers or a legal advisory role.
   - The EAC's advice will be provided to the Alliance Board.
   - The EAC Chair will be invited to attend the Board.

ANNEX A: MEMBERSHIP

Professor Effy Vayena (Chair)
Health Ethics + Policy Lab, ETH Zurich

Pamela Andana
Wits University, South Africa

Claudia Emerson
McMaster University, Canada Director, Institute on Ethics & Policy for Innovation

Sharon Kaur
University of Malaysia

Katherine Littler
Co-Lead, Global Health Ethics & Governance Unit, World Health Organization

Graeme Laurie,
Professor of Medical Jurisprudence, University of Edinburgh

Elettra Ronchi
Senior Policy Analyst, Head of Data Governance and Privacy Unit, OECD

Chair of PPPIE Expert Group to join once group has been established.