

Ebola Data Platform: Ethics Framework

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This ethics framework is intended to guide the Ebola virus disease (Ebola) data platform (the “Platform”) to promote ethical and equitable access to data on Ebola while achieving the Platform’s overall goals to increase the dissemination of knowledge and improve patient outcomes. Fulfilment of this purpose requires that the individuals and communities from whom data originated be accorded the respect and protection that is due to them, including protecting their interests, rights, safety, privacy and dignity.

This ethics framework is therefore designed to clarify the responsibilities of the Platform, data subjects, contributors, and researchers and identify issues of ethics that arise in the sharing of human data. It details a set of principles and standards that all those involved in the Platform agree to operate by.

OVERARCHING PRINCIPLES

I. Good Governance

Efforts to collect and manage the use of data about Ebola, whether clinical, laboratory, epidemiological, methodologies or other data about Ebola must include the involvement of the host country from which the data was collected (“country of origin”), and all efforts must be executed in good faith.

II. Collaboration and Capacity Strengthening

The Platform will support through collaboration, training and capacity strengthening: access to and research using the Data; as well as skills in data management, of researchers and those involved in the management and evaluation of data systems in the countries of origin.

III. Timely, Accountable Data Access

The Platform is committed to reducing barriers to data access as much as possible while balancing and maintaining the level of accountability necessary to protect the rights of data subjects and to do no harm to the individual or the community at large. The Platform is also committed to maximizing public benefit by promoting research and innovation, in order to facilitate and accelerate research.

VI. Equity and Benefits Sharing

The Platform advocates acceptance of the legal and ethical responsibility to ensure fair and equitable sharing of any benefits that arise from the use of people’s health data. The Platform is committed to promoting the adequate and timely sharing of results and benefits of data access amongst those affected by or involved in outbreak interventions, diagnostics,

treatment, research and prevention of Ebola or other essential research related to Ebola. In addition, the Platform will support access to data for research that promotes accessibility, affordability and adaptability of drugs, vaccines, and diagnostics and any other results from the use of the data for the Ebola to all countries in need, in particular those affected by Ebola outbreaks.

V. Community and Stakeholder Engagement

The Platform will engage and communicate with stakeholders, including Ebola survivors and Ebola affected families and communities, and any other interested organisations or individuals whose skills/competence directly contribute to the purpose of the Platform in order to support and stimulate the Platform.

VI. Research Agenda

The Platform agrees to promote the pursuit of a proactive, multilateral research agenda to ensure that priority questions are being answered.

VII. Compliance with Laws

The Platform will comply with all applicable laws including, without limitation, the applicable laws of the country of origin and international standards, including with respect to obtaining ethical and scientific approvals from the country of origin, as well as obtaining all relevant international ethical and scientific approvals. Where the laws or ethics requirements differ between the country of origin, any other applicable laws, and international standards, the Platform will apply the most rigorous requirements.

VIII. Transparency

The Platform is committed to operating transparently in its design and management. To that end, the Platform will share information about the names of all governance body members, details about the governance of the platform, data access policies and procedures (including what criteria must be fulfilled when making an access request, what conditions there may be on access and how to appeal decisions) as well as, wherever possible, summary reports of the meetings.

IX. Conflicts of Interest

The Platform is committed to protecting the reputation and integrity of the Platform and to ensure trust and confidence in the governance arrangement related to it by avoiding or

managing conflicts as they arise and will do so in accordance with its *Conflict of Interest Policy*.

X. Data Quality

The Platform will promote the collection and management of data paying special attention to the relevance, accuracy, timeliness, accessibility, interoperability and coherence of data to be shared. All relevant metadata, assumptions and experimental details provided by the data contributor to the Platform will be made available with data released to approved requestors. This will ensure that any work conducted from the data takes into account the context in which the data was originally produced.

XI. Disputes

All disputes on the Platform's policies and procedures will be addressed by the Steering Committee. Disputes regarding the data access decisions should be made to the Data Access Committee in the first instance. All parties involved in the Platform agree to work in good faith to settle disputes.

PRINCIPLES FOR THE PLATFORM, DATA SUBJECTS, AND CONTRIBUTORS

The Platform is committed to principles that relate to the collection, recording, processing, storage and transmission of personal data being undertaken in a lawful and fair manner. Data contributors submitting data need to satisfy themselves that they have the authority to submit the data. The Platform shall ensure that robust data security mechanisms and controls, benchmarked against national and international standards, are in place to protect the privacy and rights of the data subjects.

I. Voluntary

The Platform agrees that both the data subject and data contributor have the right to withdraw their data from the Platform at any time, such withdrawal affects the future use of that data. A request to remove data will be fulfilled within a reasonable period.

II. Ethics Oversight

Access to data will be in accordance with applicable ethical standards and approvals, including international best practice 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.

Access to data should adhere to the terms of consent agreed with the data subject. Where consent was not obtained, for example because it was collected in emergency settings for surveillance or patient management, an approach to consent and/or a waiver of consent must be approved by the responsible ethics committee of the country of origin.

III. Do No Harm

The Platform is committed to ensure that its activities shall do no harm both at the individual and community levels.

IV. Medical Confidentiality & Data Security

The Platform will uphold medical secrecy, privacy and data protection and put in place suitable technical and organisational measures to ensure data is held securely. The Platform will not share identifiable data of any person.

IV. Respect the Interests and Protect the Rights of Individuals and Communities

The Platform will respect the interests and protect the rights of the individuals and communities from where the Data originated.

V. Attribution and Accountability

The Platform will, where requested by data contributors or necessary for accountability purposes, identify the data contributor.

PRINCIPLES FOR THE PLATFORM AND RESEARCHERS

The Platform encourages the rapid dissemination of information in an equitable manner, which respects the interests of those who collect the data. To that end, the Platform will have a fair, transparent, equitable, efficient, timely, and effective system to make data accessible in order to facilitate research and encourage rapid publication. Equitable access will be promoted by sourcing central funding to host the Platform, thus enabling cost-free access to data. The Platform is also committed to maximising public benefit by strengthening and promoting research and innovation by the main Ebola-affected countries, through collaboration, training and capacity strengthening.