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DRAFT #7

Framework for Responsible Sharing of Genomic and Health-Related Data

Preamble

The sharing of genomic and health-related data for biomedical research is of key importance in ensuring continued progress in our understanding of human health and wellbeing. The challenges raised by international, collaborative research require a principled and practical Framework that brings together regulators, funders, patient groups, information technologists, and research consortia to share data. Such a Framework will facilitate responsible research conduct in global science.

This Framework provides guidance for the responsible sharing of genomic and health-related data. In particular, it highlights, and is guided by, Article 27 of the 1948 *Universal Declaration of Human Rights*. Article 27 guarantees the rights of every individual in the world "*to share in scientific advancement and its benefits*", to freely engage in responsible scientific inquiry, and at the same time "*to the protection of the moral and material interests resulting from any scientific…production of which [a person] is the author*." (Article 27 has been expanded by other international conventions and national laws, regulations, codes and policies set out in Appendix 1).

This Framework establishes a set of foundational principles for responsible research conduct and oversight of research data systems. It interprets the right to enjoy the benefits of scientific progress and its applications as being the right to engage in responsible scientific inquiry and to access and share genomic and health-related data across the translation continuum, from basic research through practical applications. It applies the right to benefit from the protection of the moral and material interests resulting from scientific productions to health-related research by recognizing the attribution rights of data producers. In addition to being founded on the right of all citizens in all countries to the benefits of science, and on the right of attribution of scientists, it also reinforces the right of scientific freedom. The Framework is guided by the enforceable human rights of privacy, non-discrimination, and procedural fairness. At the same time, the Framework considers all human rights principles as complementary and interrelated, founded as they are on respect for human dignity.

The value of this Framework is that it: offers political and legal dimensions that reach beyond the moral appeals of bioethics and provides a more robust governance framework for genomic and health-related data sharing; speaks to groups and institutions, not just individuals; stresses the progressive realization of duties; urges action by governments, industry, funders, and researchers to create an environment for responsibly sharing data; and, fosters responsible research in health by reinforcing protections in critical areas.

I. Purpose and Interpretation

The purpose of this Framework is to provide a principled and practical framework for the responsible sharing of genomic and health-related data. This Framework should be interpreted in good faith. This Framework is to be understood as a whole and the Foundational Principles and Core Elements are to be understood as complementary and interrelated, as appropriate and relevant in different contexts and cultures. The Framework will be buttressed by Codes of Conduct for guidance in particular issues such as, but not limited to, privacy, security, and ethics review.

The primary goals of this Framework are to:

A. Protect and promote the welfare, rights, and interests of groups and individuals from around the world in genomic and health-related data sharing;

B. Complement laws and regulations on privacy and data protection, as well as codes for the ethical governance of research;

C. Foster responsible data sharing and oversight of research data systems;

D. Establish a framework for greater international data sharing cooperation, collaboration, and good governance;

E. Serve as a dynamic instrument that can respond to future developments in both the science and practices of genomic and health-related data sharing; and

F. Be a tool for the evaluation of research by research ethics committees.

II. Application

This Framework may be adopted and implemented by organizations and bodies involved in genomic and health related data sharing.

A. It applies to all bodies or individuals providing, storing, accessing, managing or otherwise using genomic and health-related data, such as researchers, research participants and patient communities, research funding agencies, hospitals, research ethics committees, industry, ministries of health, and public health organizations..

III. Foundational Principles

The Foundational Principles of this Framework guide responsible data sharing. They also facilitate compliance with the obligations set by international and national law and policies.

Foundational Principles for Responsible Data Sharing

- **Promote Health and Wellbeing**
- **Respect Individuals, Families and Communities**
- **Advance Research and the Fair Distribution of Benefits**
- **Foster Trust, Integrity and Reciprocity**

IV. Core Elements of Responsible Data Sharing

The Core Elements of the Framework aim to aid in the interpretation of the Foundational Principles to individuals and organizations involved in the sharing of genomic and health-related data. The Core Elements should be interpreted in a proportionate manner that acknowledges different levels of risk and community cultural practices. **This Framework applies to data that has been approved for use by competent bodies in compliance with national and international laws and that respect restrictions on downstream uses.** Endorsement of the Framework does not preclude the development of particular guidance via Codes of Conduct for specific populations (e.g. children) or issues (e.g. privacy, security, ethics review, etc.).

Core Elements for Responsible Data Sharing

1. Transparency

1.1. Developing clearly defined and accessible information on the purposes, processes, procedures and governance frameworks for data sharing.

1.2. Providing information on the purpose, collection, use and exchange of genomic and health-related data, including: data transfer to third parties, international transfer of data, terms of access, re-identifiability and limits to anonymity or confidentiality of data, communication of results to individuals and/or groups, commercial involvement, and proprietary claims.

1.3. Implementing procedures for fairly determining requests for data access and exchange.

2. Accountability

2.1. Putting in place systems for data sharing that respect this Framework.

2.2. Tracking the chain of data exchange.

2.3. Developing processes to identify and manage conflicts of interest.

2.4. Implementing mechanisms for handling complaints related to data misuse; for identifying and managing breaches; and for instituting appropriate sanctions.

3. Data Security and Quality

3.1. Storing and processing the data collected, used and transferred in a way that is accurate, verifiable, unbiased, and current, so as to enhance their interoperability and replicability while preserving their long-term searchability and integrity.

3.2. Ensuring feedback mechanisms on the utility, quality, security, and accuracy of data, and their annotations, with a view to improving quality and interoperability and re-use by others.

3.3. Installing strict data security measures to prevent unauthorized access, data loss and misuse..

4. Privacy, Data Protection and Confidentiality

4.1. Complying with applicable privacy and data protection regulations, along with assurances that confidentiality and privacy are appropriately protected when data are collected, used and exchanged. Depending on the nature of the data, and whether it is identifiable, coded or anonymized, different levels of privacy and data protection may be necessary.

4.2. Foregoing any attempt to re-identify anonymized data unless where expressly authorized by law, or when there are compelling and just grounds.

5. Minimizing Harm and Maximizing Benefits

5.1. Conducting data sharing with a view towards minimizing harms and maximizing benefits to not just those who contribute their data, but also to society and health care systems as a whole, particularly where data pertains to people based in more disadvantaged parts of the world.

5.2. Considering the realistic harms and benefits of data sharing on individuals, families and communities, including opportunity costs.

5.3. Undertaking a proportionate assessment of the benefits and risks of harm in data sharing, which is periodically monitored according to the reasonable foreseeability of such harms and benefits. Such an assessment may also incorporate mechanisms that track subsequent harms, should they materialize, so as to help inform future policy.

6. Recognition and Attribution

6.1. Designing systems of data sharing with a view towards recognition and attribution that are meaningful and appropriate to the medium or discipline concerned and which provide due credit

and acknowledgement of all who contributed to the results.

6.2. Extending recognition and attribution equally to secondary or downstream uses and applications. All parties should act in good faith to ensure that the connections to original sources of data are maintained in the public record to the extent permissible by law.

7. Sustainability

7.1. Addressing projects and systems for sharing genomic and health-related data at the earliest stage so as to ensure the sustainability of the data generated for future use, including their archiving and identifiability.

8. Accessibility and Dissemination

8.1. Ensuring accessibility of data for research approved by competent bodies, and for data sharing purposes.

8.2. Promoting collaborative partnerships and data sharing that can generate maximum value, along with the harmonization of deposit, management and access procedures and use as a means to promote accessibility.

8.3. Publishing and disseminating research results, whether positive, negative or inconclusive, depending on the nature of the data. Dissemination of research results should be conducted in a way that promotes broad access and minimizes obstacles to data sharing.

8.4. Making data and research results widely available in a manner that promotes scientific collaboration and reproducibility.

V. Implementation Mechanisms and Amendments

A. Persons and entities listed in section 2 of this Framework should take all appropriate measures, whether of a legislative, administrative or other character, to give effect to the Foundational Principles and Core Elements set out in this Framework in accordance with the international law of human rights and should, by means of all appropriate measures, promote their implementation.

B. Any persons or entities listed in section 2 of this Framework may propose one or more amendments to the present Framework by communicating the amendments to the Regulatory and Ethics Working Group of the Global Alliance for Genomics and Health (the ‘REWG’). The Regulatory and Ethics Working Group shall publicly circulate such amendments for comments and possible inclusion in the Framework.

C. The REWG, in collaboration with biomedical, patient advocacy, and ethical and policy organizations and committees, will track the adoption of this Framework and its application

through subsequent Codes of Conduct, as well as routinely review its provisions in order to keep the Framework continuously up-to-date with new advances in basic research and technology, and ethical and legal developments.

VI. Acknowledgements

This *Framework for Responsible Sharing of Genomic and Health-Related Data* is the result of the work of many people and committees. Developed under the auspices of the Global Alliance for Genomics and Health, the Framework was initially formulated by an international committee (Regulatory and Ethics Working Group) representing a wide spectrum of the bioethics, genomics, and clinical communities. Collaborative input was provided from biomedical, patient advocacy, and ethical, policy and legal organizations, committees, and projects from all regions of the world. These include, but are not limited to: the Public Population Project in Genomics and Society (P3G), the International Cancer Genome Consortium (ICGC), H3Africa, Inserm, the Biobank Standardisation and Harmonisation for Research Excellence project (BioSHaRE), the PErsonalised Risk Stratification for Prevention and Early deteCTIon of breast cancer project (PERSPECTIVE), the International Society for Biological and Environmental Repositories (ISBER), the International Rare Disease Research Consortium (IRDiRC), and other Global Alliance for Genomics and Health Working Groups.

Appendix 1

Foundational Human Rights Instruments

* Universal Declaration of Human Rights (UN 1948) (Article 27)
* International Covenant on Economic, Social and Cultural Rights (UN 1966) (Article 15)

Ethical and Legal Codes and Policies Guiding Data Sharing Behavior

- Constitution of the World Health Organization (WHO 1946)
- Bermuda Principles on Human Genome Sequencing (1996)
- Universal Declaration on the Human Genome and Human Rights (UNESCO 1997)
- The Convention on Human Rights and Biomedicine (Council of Europe 1997)
- Statement on DNA Sampling: Control and Access (HUGO 1998)
- Statement on Human Genomic Databases (HUGO Ethics Committee 2002)
- Declaration of Ethical Considerations regarding Health Databases (WMA 2002)
- International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS, WHO 2002)
- Budapest Open Access Initiative (2002)
- Sharing Data from Large-scale Biological Research Projects: A System of Tripartite Responsibility (Fort Lauderdale Statement, 2003)
- International Declaration on Human Genetic Data (UNESCO, IBC 2003)
- European Society of Human Genetics: Data Storage and DNA Banking for Biomedical Research (ESHG 2003)
- Universal Declaration on Bioethics and Human Rights (UNESCO 2005)
- Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research (Council of Europe 2005)
- Recommendation Rec (2006) 4 of the Committee of Ministers to Member States on Research on Biological Materials of Human Origin (Council of Europe 2006)
- OECD Principles and Guidelines for Access to Research Data from Public Funding (OECD 2007)
- International Ethical Guidelines for Epidemiological Studies (CIOMS, WHO 2008)
- 2008 Best Practices for Repositories: Collection, Storage, Retrieval and Distribution of Biological Material for Research (ISBER 2008)
- Recommendations from the 2008 International Summit on Proteomics Data Release and Sharing Policy (Amsterdam Principles, 2008)
- Guidelines for Human Biobanks and Genetic Research Databases (OECD 2008, 2009)
- Toronto Statement on Prepublication Data Sharing (2009)
- Joint Statement by Funders of Health Research (2011)
- Responsible Conduct in the Global Research Enterprise: A Policy Report (InterAcademy Council 2012)
- Declaration of Helsinki (WMA 2013)
- Guidelines governing the Protection of Privacy and Transborder Flows of Personal Data (OECD 2013)