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Global Alliance for Genomics and Health: Consent Policy

Preamble

The Global Alliance for Genomics and Health ("GA4GH") is an international, non-profit coalition of individuals and organizations working in healthcare, research, disease advocacy, life science, and information technology dedicated to improving human health by maximizing the potential of genomic medicine through effective and responsible data sharing. Its mission is "to accelerate progress in human health by helping to establish a common framework of harmonized approaches to enable effective and responsible sharing of genomic and clinical data, and by catalyzing data sharing projects that drive and demonstrate the value of data sharing."

The *Framework for Responsible Sharing of Genomic and Health-Related Data*[1] (hereinafter, the "*Framework*") is a document developed by the GA4GH that sets forth a harmonized and human rights approach to responsible data sharing through Foundational Principles and Core Elements. Elaborating on the general principles and guidance offered in the *Framework*, the GA4GH has created Policies that provide specific guidance on particular issues. These Policies can help both individuals and organizations that support the mission of the GA4GH make improvements or adopt specific best practices for responsible data sharing and governance processes.

This document is the GA4GH's Consent Policy. The objective of this Policy is to guide the sharing of genomic and health-related data in a way that respects autonomous decision-making while promoting the common good of international data sharing.

I. Context

1. Context. The *Framework* applies to use of data that have been consented to by data donors[2] (or their legal representatives) and/or approved for use by competent authorities or institutions in compliance with national and international laws, general ethical principles, and best practices that respect restrictions on downstream uses.[3] This includes recognition that the consent process is situated within and overseen by appropriate governance mechanisms. This Policy is concerned with the process of data sharing and not the specific category of data (e.g., identifiable, coded, or anonymous) to be shared, as each will have specific requirements depending on context. Therefore, this Policy focuses both on consent aspects that enable or encourage the use of data and provides guidance for data sharing in future protocols. It can help to determine if data sharing is indeed covered in the existing consent or if re-contact with notification and opt out or, re-

[1] Available at http://genomicsandhealth.org/about-the-global-alliance/key-documents/framework-responsible-sharing-genomic-and-health-related-data.
[2] This terminology is used to reflect its use in the *Framework*, however other terms can be used such as data contributor.
[3] A list of suggested procedural guidance can be found in Appendix 2.

consent or other forms of approvals or social engagement are necessary to enable data sharing. It can also help to ensure that genomic and health-related data within the GA4GH ecosystem are harmonized across organizations, bodies and countries to the greatest extent possible.

2. Principles. This Policy builds on the Foundational Principles set forth in the *Framework*, namely:

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

    Additionally, this policy builds on the principle that the *Framework* applies to "all entities or individuals providing, storing, accessing, managing or otherwise using genomic and health-related data, including data donors, users, and producers." It also refers directly to specific core elements of the *Framework*, as noted under Section II. Reflecting this position, this Policy applies to those having obtained consent from data donors or contemplating seeking consent for data sharing or for further data sharing, as well as those who have been asked to give their consent. This Policy applies to all parties, asking them to consider consent for data sharing in a way that respects the provisions of the *Framework*.

    This Policy also recognizes that there is more than one way to create and maintain a consent relationship and to respect the diversity of approaches and technologies for meaningful and ongoing engagement used in different countries.

    Finally, this Policy reaffirms that seeking, following and renewing the terms of a valid consent for international data sharing shows respect for those donating data as well as constituting best practice for those using and sharing data.

3. Purpose. The purpose of this Policy is to provide principled and practical guidance on consent issues related to the sharing of genomic and health-related data in order to respect the principles of the *Framework*.

    This Policy is founded on these basic principles:

    i. Consent is an open, communicative and, ideally, continuing relationship.

    ii. There is an intention to share data across clinical/research groups and/or jurisdictions and national borders with appropriate approvals in place.

    iii. Plans for data sharing should be transparent, understandable and accessible.

    iv. Data donors have a right to not participate in international data sharing or, if participating, are able to withdraw, with the understanding that it may not be possible to retrieve and/or destroy data once shared.

    v. Data users and data producers will abide by applicable regulations and ethical norms when seeking and conducting international data sharing.

4. Interpretation. Without ascribing legal meaning, this Policy should be interpreted in good faith and is to be understood as a whole. The Best Practices in Section II are to be understood as complementary and interrelated, and as appropriate and relevant in different contexts, countries and cultures. For the purposes of this Policy, "data sharing" includes data transfer or data exchange between data users, or where data are made available to secondary researchers, either openly or under specified access conditions. It should not be confused with the issue of the return of health-related data to individuals or their rights to access their health-related data. As noted, this Policy applies to the use of data that have been consented to by donors (or their legal representatives) and/or approved for use by competent authorities or institutions in compliance with national and international laws, general ethical principles, and best practices that respect restrictions on downstream uses.

5. Application. It is expected that this Policy will be useful to organizations and bodies involved in genomic and health-related data sharing, and in particular the Individual and Organizational Members of the GA4GH. These persons, organizations and bodies include, but are not limited to, researchers, research participants and patient communities, publishers, research funding agencies, data protection authorities, hospitals, research ethics committees, industry, ministries of health, and public health organizations.

II. Consent Best Practices

The Best Practices of this Policy guide the sharing of genomic and health-related data to promote and protect respect for the commitment to informed consent. They also facilitate compliance with the obligations and norms set by international and national laws and policies. Where appropriate, these Best Practices are linked with other best practices identified as promoting informed consent in genomic and health-related data sharing. These Best Practices are grouped under Core Elements of the *Framework* and should be interpreted in a proportionate manner that acknowledges different levels of risk and community cultural practices and, where appropriate, different contexts for data sharing and use.

Consent is one of the bedrock principles underlying the ethical conduct of clinical practice and research involving humans. The practice of seeking, giving and renewing informed consent shows respect for the ability of data donors to make their own decisions, as well as respect for the practices of medicine and research. Consent, in any form it takes, will only be valid if the data donor (including the legal representative of a minor/incapable adult) is freely capable of consenting and is given sufficient time and information on which to make an informed decision. Yet fully informed consent is difficult to achieve and some possible future uses of a person's data may not be known when consent is considered. If consent becomes too specific, or is too vague, it may be difficult to share that data in a respectful way. The following best practices can help all parties share data in an ethically responsible manner.

Transparency

- It should be clear in any consent materials, and in discussions with data donors regarding consent, that genomic and health-related data will be shared.
- Any details of data sharing, such as the data sharing plan, should be presented in such a way as to be understandable.
- Details of actual or future data sharing should be provided in plain language through different means, as individuals learn and understand in different ways, for example, visually through pictures, oral communications, video, bulletins and web-based tools etc.
- In case of substantial protocol changes, consent materials should be revised and changes should be tracked. Consideration should be given to how any changes might affect the sharing of the data already collected or of any data to be collected in the future.

Accountability

- The consent process, in any form it takes, should be properly documented.
- Consent materials and data sharing plans should be available for inspection and discussion with interested parties.
- Consent materials and data sharing plans should be updated and made available in response to new regulations and policies by responsible individuals within an organization or entity.
- Procedures should be in place to receive and respond to consent withdrawal, complaints or inquiries about policies and practices relating to consent to the sharing of genomic and health-related data. The procedures should be easily accessible and simple to use.

Data Quality and Security

- Any proof of consent, whether verbal or with a signature (electronic or not), should be securely stored in accordance with local governance requirements, and available for inspection if needed.
- Data security measures should be put into place to ensure that electronic consent materials are retrievable and safe from deliberate or inadvertent damage.

Privacy, Data Protection and Confidentiality

- Consent materials should specify what category of data will be shared (e.g., identifiable, coded, anonymous) and how data will be protected in accordance with applicable laws and/or guidelines.

Risk-Benefit Analysis

- Special attention should be placed on the protections afforded to vulnerable persons or populations in the seeking and obtaining of consent, to prevent exploitation and facilitate proper representation without unnecessarily excluding them from research.
- Consent materials must specify how data donors can withdraw from a research study or the sharing of clinical or research data, and state that if data have already been shared it may be impossible to retrieve and/or destroy that data.

Accessibility and Dissemination

Sharing prospective data

- Consent materials should indicate that a data sharing plan has been developed and approved by a competent authority, such as a research ethics board, research ethics committee, institutional review board, etc.
- Consent materials should indicate that data sharing plans and Data Transfer Agreements, based on best practice guidance, have been developed.

Sharing legacy data

- Prior to sharing legacy data, existing consent materials and associated policy documents should be assessed to determine if international data sharing was foreseen.
- If international data sharing was not foreseen, careful consideration should be given to whether international data sharing is justifiable based on the potential risks and benefits of sharing the data.
- If international data sharing is judged to be appropriate, consideration should be given as to how consent or agreement can be obtained, or if not, how a waiver can be obtained.
- If re-contact with notification and opt-out, or re-consent for international data sharing is possible and practical, data donors should be approached with details of the data sharing plans and be allowed to opt-out or provide additional informed consent for international data sharing respectively, if they so agree.
- If neither re-contact with notification and opt-out, or re-consent for international data sharing is possible, authorization to proceed with research should be sought from a competent authority.

III. Implementation Mechanisms and Amendments

1. Organizations and bodies supporting this Policy should take all reasonable and appropriate measures, whether of a regulatory, contractual, administrative or other character, to give effect to this Policy and promote its implementation, monitoring and enforcement. Procedures and policies

should be transparent and accessible. Attention should be paid to the interrelation of this Policy with other GA4GH Policies (e.g. Privacy and Security Policy, Accountability Policy).

2. Any persons, organizations or bodies supporting this Policy may propose one or more amendments to the present Policy by communicating the amendments to the GA4GH's Regulatory and Ethics Working Group (REWG). The REWG shall publicly circulate such amendments for comments and possible inclusion in this Policy.

3. The REWG, in collaboration with biomedical, patient advocacy, and ethical and policy organizations and committees, will track the adoption of this Policy and its application. It will also routinely review its provisions, be aware of advances in basic research and technology, and ethical and legal developments, and attempt to ensure that this Policy is fit for purpose.

IV. Acknowledgements

This Policy is the result of the work of many people and committees. Developed under the auspices of the GA4GH's Regulatory and Ethics Working Group, the Policy was formulated by an international committee (Consent Policy Task Team) representing a wide spectrum of the law, security, bioethics, genomics, life science industry, and clinical communities. Collaborative input was provided from individuals as well as biomedical, patient advocacy, and ethical, policy and legal organizations, committees, and projects from all regions of the world. These include: the Centre of Genomics and Policy (McGill University); the National Institutes of Health (NIH, United States); PHG Foundation (United Kingdom); Roche Molecular Systems, Inc.; and the Public Population Project in Genomics and Society (P3G, McGill University).

Appendix 1

Definitions and Glossary
[under construction – P^{3}G/BBMRI-ERIC]

Appendix 2

Examples of Procedural Guidance

- National Health and Medical Research Council, Australian Research Council, and Australian Vice-Chancellors' Committee, *National Statement on Ethical Conduct in Human Research* (2007) [link]
- Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement - Ethical Conduct for Research Involving Humans* (2010) [link]
- Council for International Organizations of Medical Science (CIOMS), *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (2002) [link]
- Council of Europe, *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, Oviedo* (1997) [link]
- Council of Europe, *Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research* (2005) [link]
- *Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data* (1995) [link]
- H3Africa, *Guidelines for Informed Consent* (2014) [link]
- Organisation for Economic Co-operation and Development (OECD), *Guidelines on the Protection of Privacy and Transborder Flows of Personal Data* (2013) [link]
- Organisation for Economic Co-operation and Development (OECD), *Guidelines on Human Biobanks and Genetic Research Databases* (2009) [link]
- *The Nuremberg Code* 1949 [link]
- The Public Population Project in Genomics and Society (P^3G), *Generic Access Agreement* (2013) [link]
- US Office for Human Research Protections, *Informed Consent* [link]
- US Department of Health and Human Services, *Federal Policy for the Protection of Human Subjects ('Common Rule'), 45 CFR 46.116(d)* (2009) [link]
- US National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *Ethical Principles and Guidelines for the Protection of Human Subjects of Research [Belmont Report]* (1979) [link]
- World Medical Association, *Declaration of Helsinki. Ethical Principles for Medical Research Involving Human Subjects* (2013) [link]
- World Medical Association, *International Code of Medical Ethics* (2006) [link]

Policy Revision History

Policy Number/Version	Date Effective	Summary of Revisions
POL 002 / v. 1.0	June 2015	Original document