

# Global Alliance for Genomics & Health

Collaborate. Innovate. Accelerate.

## Human Rights Approach

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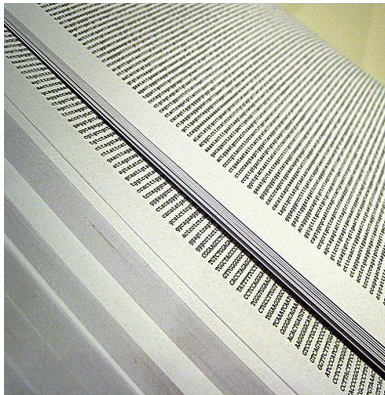


**Global Alliance**  
for Genomics & Health  
Collaborate. Innovate. Accelerate.

I have no Conflicts of Interest to Declare.

# The Challenge

Unparalleled generation of  
human genetic data



How do we unlock its potential?



In a way that allows data to be shared  
on a global level



Thus empowering new knowledge, new  
diagnostics and new therapeutics for  
patients and populations



## Mission



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 Global Alliance will NOT *directly*:



Generate or store data

Perform research or care for patients

Interpret genomes

Be exclusive to entities that have and share data

## Working Groups



The Clinical Working Group aims to enable compatible, readily accessible, and scalable approaches for sharing clinical data and linking genomic data. Clinical Working Group strives to address both research and clinical use scenarios and be physician-oriented, researcher-focused, and patient-centered.



The Data Working Group concentrates on data representation, storage, and analysis of genomic data, including working with academic and industry leaders to develop approaches that facilitate interoperability. physician-oriented, researcher-focused, and patient-centered.



The Regulatory and Ethics Working Group focuses on ethics and the legal and social implications of the Global Alliance, including harmonizing policies and standards, and developing forward-looking consent, privacy procedures, and best-practices in data governance and transparency.



The Security Working Group leads the thinking on the technology aspects of data security, user access control, and audit functions, working to develop or adopt standards for data security, privacy protection, and user/owner access control.

## Current demonstration projects



- Undertaken by the members, not by GA4GH as an organization
- Catalyzed and supported by GA4GH coordinators and Working Groups
- Their purpose: to drive learning, to identify requirements, to evaluate value and to coordinate activity



Beacon Project



Matchmaker Exchange

Matchmaker Exchange



BRCA Challenge

## Universal Declaration of Human Rights, (1948)

### “The Right to Science”

27(1)

“**Everyone** has the right freely to participate in the cultural life of the community, to enjoy the arts and **to share in scientific advancement and its benefits.**”

### “The Right to Recognition”

27(2)

“Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.”



## Article 15



### *Article 15*

1. The States Parties to the present Covenant recognize the right of everyone:

[...]

(b) To enjoy the benefits of scientific progress and its applications;

[...]

3. The States Parties to the present Covenant undertake to respect the freedom indispensable for scientific research and creative activity.

4. The States Parties to the present Covenant recognize the benefits to be derived from the encouragement and development of international contacts and co-operation in the scientific and cultural fields.

*International Covenant on Economic, Social and Cultural Rights, 1966*

## Legal Force

- Dual rights rendered legally binding by the International Covenant on Economic, Social and Cultural Rights (ICESCR) (1966) – Article 15.
- 164 States have ratified the ICESCR.
- States are bound to implement the treaty in their national laws.

The Right to Science à  
Actionable

## Articles 18, 19



### Article 18

States should make every effort [...] to continue fostering the international dissemination of scientific knowledge concerning the human genome, human diversity and genetic research and, in that regard, to foster scientific and cultural co-operation, particularly between industrialized and developing countries.

### Article 19

(a) In the framework of international co-operation with developing countries, states should seek to encourage measures enabling:

[...]

(iii) developing countries to benefit from the achievements of scientific and technological research so that their use in favour of economic and social progress can be to the benefit of all;  
(iv) the free exchange of scientific knowledge and information in the areas of biology, genetics and medicine to be promoted.

(b) Relevant international organizations should support and promote the initiatives taken by states for the above-mentioned purposes.

*Universal Declaration on the Human Genome and Human Rights, 1997*

## Article 15(1)(a-e)

### Article 15 – Sharing of benefits

1. Benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community, in particular with developing countries. In giving effect to this principle, benefits may take any of the following forms:

[...]

(e) access to scientific and technological knowledge.

*Universal Declaration on Bioethics and Human Rights, 2005*



# Why a Human Rights Approach to Data Sharing?

- ∨ The more globalized public health becomes, the more we will need to turn to human dignity as the foundation for the human rights of citizens;
- ∨ Recourse to human rights justified on the grounds that bioethics suffers from too many divergent norms.



*Adorno, R, "Human dignity and human rights as a common ground for global bioethics", J Med Philos, 2009, 34(3): 223-40.*

✓ The human rights approach is already engrained in international law, positioning it to handle the translational and harmonization issues; it has both political and legal dimensions, reaching beyond “the moral appeals of bioethics”; it applies both to individuals and to groups; it reaches past only negative duties to progressive ones that urge action; and it offers protection in privacy, anti-discrimination/fair access, and procedural fairness.

✓ A human rights approach will bolster existing principles and “provide a legal framework for enactment and accountability”.

*Knoppers, BM et al, “A human rights approach to an international code of conduct for genomic and clinical data sharing”, Hum Genet, 2014, 133(7): 895-903;*

*Knoppers, BM, “International ethics harmonization and the global alliance for genomics and health”, Genome Medicine, 2014, 6(3).*

√ “Human rights are a shared, internationally recognized framework”, making it a helpful foundation for the creation of cross-jurisdictional/harmonized standards;

√ “Human rights call for a legal and political system that protects researchers and research subjects”, meaning that it has the capacity to go beyond the ethical responsibilities of individuals and to encompass government responsibilities, including the obligation for the government to create protections (including: access to justice, access to information, due process, accountability, and reparations).

*Harris, TL and Wyndham, JM, “Data Rights and Responsibilities: A Human Rights Perspective on Data Sharing”, J Empir Res Hum Res Ethics, 2015, 10(3): 334-7.*



√ “The health and human rights linkage, as seen from the public health side, proposes—based at this time more on insight and experience than data—that modern human rights provides a better guide for identifying, analyzing and responding directly to critical societal conditions than any framework inherited from the biomedical or recent public health tradition. Thus, promoting and protecting health is proposed to depend upon the promotion and protection of human rights and dignity”;

√ Human rights approach will help to shift the focus from individual to collective responsibility for health.

*Mann, J, “Health and Human Rights: If Not Now, When?”, American Journal of Public Health, 2006, 96(11): 1940-3.*

“[W]hereas public health practice adopts collectivist principles that emphasize utilitarian and population-based benefits, genomic (and especially personalized) medicine is squarely grounded in an individualist ethic that emphasizes autonomous decision-making for personal benefits”, creating very different ethical priorities, the gap between which can be best managed/bridged through a human rights approach.



*Meslin, EM and Graba, I, “Biobanking and public health: is a human rights approach the tie that binds?”, Hum Genet, 2011, 130(3):451-63.*

# Content of the Right to Science

1. access by everyone without discrimination to the benefits of science and its applications;
2. opportunities for all to contribute to the scientific enterprise
3. the freedom indispensable for scientific research;
4. participation of individuals and communities in decision-making;
5. conservation, development and diffusion of science and technology.

(UNESCO, *Venice Statement* 2009)

UNESCO *Venice Statement* (2009)

Identified roles of States, the private sector/commercial enterprise, and the scientific community.



AAAS (2010)

Scientific community must nurture awareness of broad social context and human rights implications



GA4GH (2014)

ACTIVATING the Right to Science



Framework

Policies

Tools

# GA4GH Regulatory and Ethics Initiatives



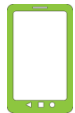
Accountability



Ageing and Dementia



BRCA Challenge  
Ethico-Legal



Mobile Health Consent



Data Protection  
Regulation



Data Sharing  
Lexicon

Ethics Review  
Equivalency



Participant Values



Machine Readable Consent



Participant Unique Identifiers

Paediatric



Registered Access



## GA4GH Framework

“It interprets the right of all people to share in the benefits of scientific progress and its applications as being the duty of data producers and users 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 recognizes the rights of data producers and users to be recognized for their contributions to research, balanced by the rights of those who donate their data. In addition to being founded on the right of all citizens in all countries to the benefits of the advancements of science, and on the right of attribution of scientists, it also reinforces the right of scientific freedom.”

*Global Alliance for Genomics and Health, “Framework for Responsible Sharing of Genomic and Health-Related Data”*

