Sharing Genomic Data: The Global Alliance for Genomics and Health

Copenhagen
September 2015

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Obstacles in Genomics

- ## Lack of policy harmonization

- ## Lack of structural support

- ## Legal and ethical hurdles

- ## Cultural barriers

B. M. Knoppers, J. R. Harris, I. Budin-Ljøsne, E. S. Dove, A human rights approach to an international code of conduct for genomic and clinical data sharing. *Human Genetics* **133, 895-903 (2014).**

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

Organizational Members

Global Alliance for Genomics & Health

344+ ORGANIZATIONAL MEMBERS

34 COUNTRIES

Global Alliance members include:

1. Universities and research institutes

2. Academic medical centers and health systems

3. Disease advocacy organizations and patient groups

4. Consortia and professional societies

5. Funders and agencies

6. Life science and information technology companies

Global Alliance for Genomics & Health (GA4GH)

Collaborate. Innovate. Accelerate.

THE GA4GH does **NOT**:

• Generate or store data

• Perform research or care for patients

• Interpret genomes

• Collaborate exclusively with entities that have
and share data

GA4GH *Framework for Responsible Sharing of Genomic and Health-Related Data*

- Current frameworks are founded on the principle of protection from harm. In contrast,
- GA4GH Framework aims to **activate** the right to science and the right to recognition for scientific production by promoting responsible data sharing.

(http://genomicsandhealth.org/framework)

Human Rights Foundation

Global Alliance
for Genomics & Health

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 for Scientific Production"

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."

Right to Science = Access to Data

Image based on American Association for the Advancement of Science (AAAS, 2010)
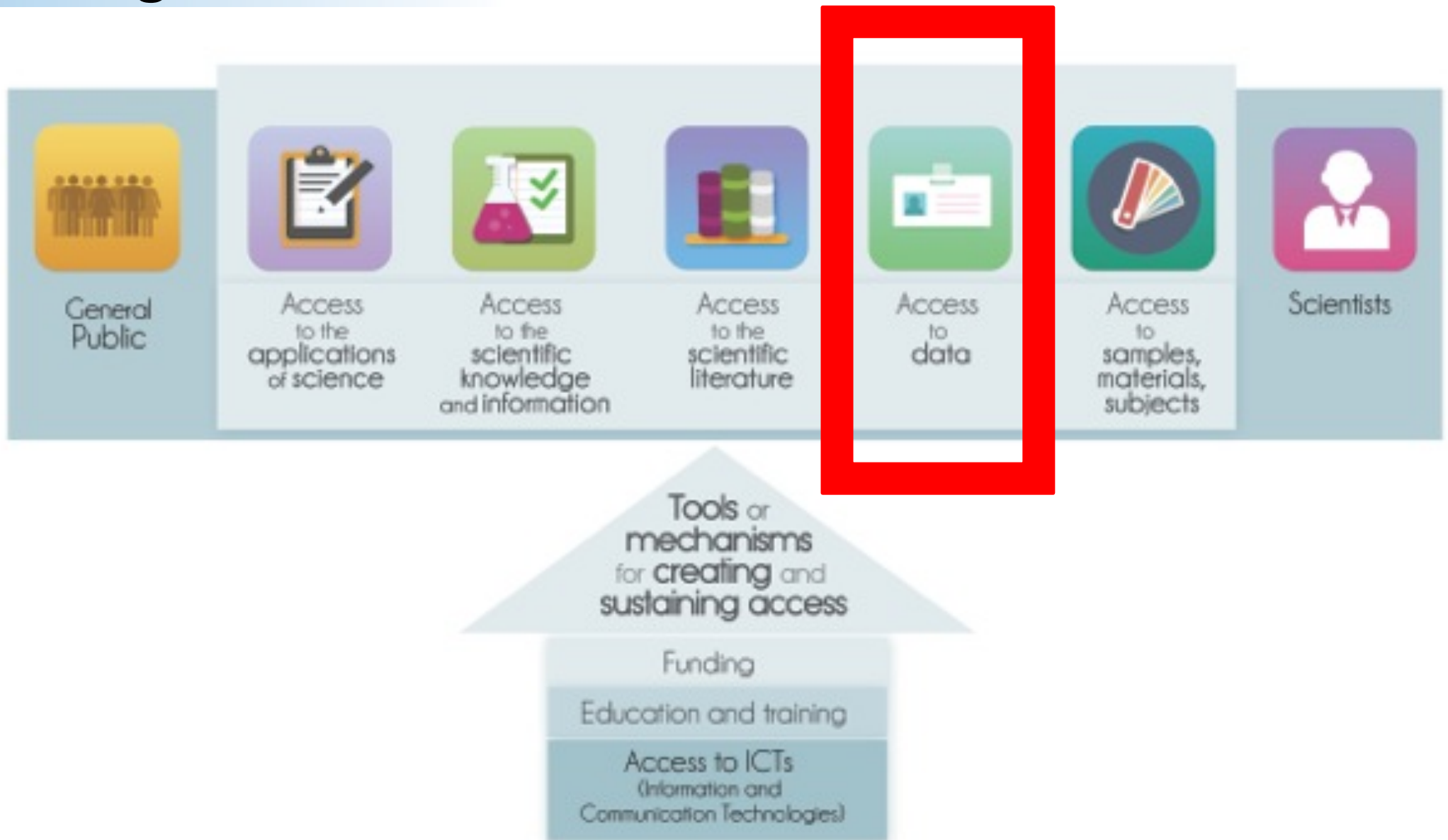
UNESCO *Venice Statement*

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

AAAS

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

GA4GH

ACTIVATING the Right to Science

Framework

Policies

Tools

Why Human Rights?

- Universalizing force
- Political and legal dimensions that reach beyond the moral appeals of bioethics
- International legal force
- Belong to groups as well as individuals (reciprocity)
- Impose positive duties on governments and private actors

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 →
Actionable**

Strong protection in 3 critical areas

Contours of responsible access, sharing, and attribution delineated by other human rights:

1. privacy;

2. anti-discrimination and fair access; and

3. procedural fairness.

Framework for Responsible Sharing of Genomic and Health-Related Data

Global Alliance for Genomics & Health

Available in 10 other languages on the GA4GH website. Thanks to all who contributed!

- Arabic   إطار لتبادل المسؤول للعملومات الجينومية والمتصلة بالصحة

- Chinese   基因组学与健康相关数据负责任的共享框架

- French   Cadre pour un partage responsable des données génomiques et des données de santé

- Greek   Πλαίσιο για την Υπεύθυνη Κοινοχρησία Γονιδιωματικών και άλλων Ιατρικών Δεδομένων

- Japanese   **ゲノム及び健康関連データの責任ある共有に関する枠組み**

- Portuguese   Framework para Compartilhamento Responsável de Dados Genômicos e Relacionados à Saúde

- Spanish   Marco de actuación para el uso compartido responsable de datos genómicos y relativos a la salud

- German   Rahmenkonzept für die den verantwortungsvollen Datenaustausch genomischer und gesundheitsbezogener Daten

- Hindi   जीनोमिकी और स्वास्थ्य संबंधी डेटा को उत्तरदायित्वपूर्ण रूप से साझा करने के लिए रूपरेखा

Framework for Responsible Sharing of Genomic and Health-Related Data

Global Alliance
for Genomics & Health

Aims

- Foster responsible data sharing;

- Protect and promote the welfare, rights, and interests of groups and individuals who donate their data;

- Provide benchmarks for accountability;

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

- Serve as a dynamic instrument.

Foundational Principles

- Respect Individuals, Families and Communities;

- Advance Research and Scientific Knowledge;

- Promote Health, Wellbeing and the Fair Distribution of Benefits; and,

- Foster Trust, Integrity and Reciprocity.

Framework for Responsible Sharing of Genomic and Health-Related Data

Global Alliance
for Genomics & Health

<u>Core Elements for Responsible Data Sharing</u>

- Transparency

- Accountability

- Engagement

- Data Quality and Security

- Privacy, Data Protection and Confidentiality

- Risk-Benefit Analysis

- Recognition and Attribution

- Sustainability

- Education and Training

- Accessibility and Dissemination

Policies: Consent

- **Purpose:** To guide international data sharing in a way that respects autonomous decision making while promoting the common good.

- Gives principled and practical guidance on consent issues:
    - Transparency
    - Privacy Safeguards
    - Withdrawal
    - Consent to access policies and terms
    - Sharing of Legacy Data
        - Notification and opt-out, or re-consent, for international data sharing if possible and practical. Otherwise seek authorization from competent authority.

Policies: Privacy and Security

- How to manage privacy and security risks and related expectations?

- How to ensure data use is consistent with individuals' expectations, and respects the rights of individuals?

- **Consent:** Data should be used strictly in accordance with the Data Donor's consent for use and sharing, and/or the terms and conditions of authorization for use by competent bodies

- **Proportionate Safeguards:** Data privacy safeguards should be proportionate to the sensitivity, nature, and possible benefits, risks, and uses of the Data

- Security: **organizational, technical and physical measures** to manage risks to privacy and data integrity.

Policies: Accountability

- Sets forth how Members of the Global Alliance can be governed and held accountable for the trust they engender in the responsible sharing of genomic and clinical data.

- Explores mechanisms to **promote** responsible data sharing, as well as to **prevent** and appropriately **sanction** data misuse.

- Possible Inclusion: Why are you NOT sharing, if the **participant consented** to sharing?

Clinical

Clinical Cancer Genome - Cancer Data Sharing
- White Paper + Survey/paper

Clinical Cancer Genome - Actionable Cancer Genome Initiative
- Opinion paper + Standard

eHealth - Pedigree Consent
- Standard

eHealth - Family History
- Tool + Standard

eHealth - Federated Queries
- Standard

eHealth - Catalogue of Activities
- Tool

eHealth - Data Sharing
- White paper

Phenotype Ontologies - Rare Diseases
- Use cases

Phenotype Ontologies - Cancer / Complex Diseases

Data

Benchmarking
- Standard (variant calling benchmark toolkits)

Containers and Workflows
- Standard (interoperable GA4GH APIs with open source)

File Formats
- Standard (file formats)

Genotype2Phenotype Association
- Standard

Metadata
- Standard (metadata schema)

Reference Implementation
- Standard (GA4GH API)

Reference Variation
- Standard (graph-based reference)
- Implementation

RNA and Gene Expression
- Standard (RNA sequence reads)

Variant Annotation
- Standard (data representation)

Regulatory and Ethics

Accountability
- Policy (accountability)

Ageing and Dementia
- Policy (data sharing in vulnerable populations) + Tools (authorization/consent)

BRCA Ethico-Legal and Engagement
- Policy (review of data protection and liability issues)
- Tool (tiered access model)
- Tool (authorization/consent)
- Tool (patient advocacy network)

Data Protection Regulation
- Communications as needed

Data Sharing Lexicon
- Tool (Catalogue)

Ethics Review Equivalency
- Resource (models that allow for mutual recognition of ethics review)

Individual Access
- Policy (patent access to raw genomic data)
- Tool (access process)

Machine-Readable Consent
- Standard (data use types in consent forms)

Paediatric
- Policy + Standard + Resource

Privacy Breach Notification
- Resource (review of breach notification laws)

Registered Access
- Tool (definition and framework for intermediate tier of access)

Security

Cloud Security
- Policy (guidance for cloud security providers)
- Implementation

Incident Response
- Policy

Security Infrastructure
- Policy

Software Security
- Policy
- Implementation

Public Population Project in Genomics and Society (P³G)

www.p3g.org

International Policy interoperability and data Access Clearinghouse (IPAC)
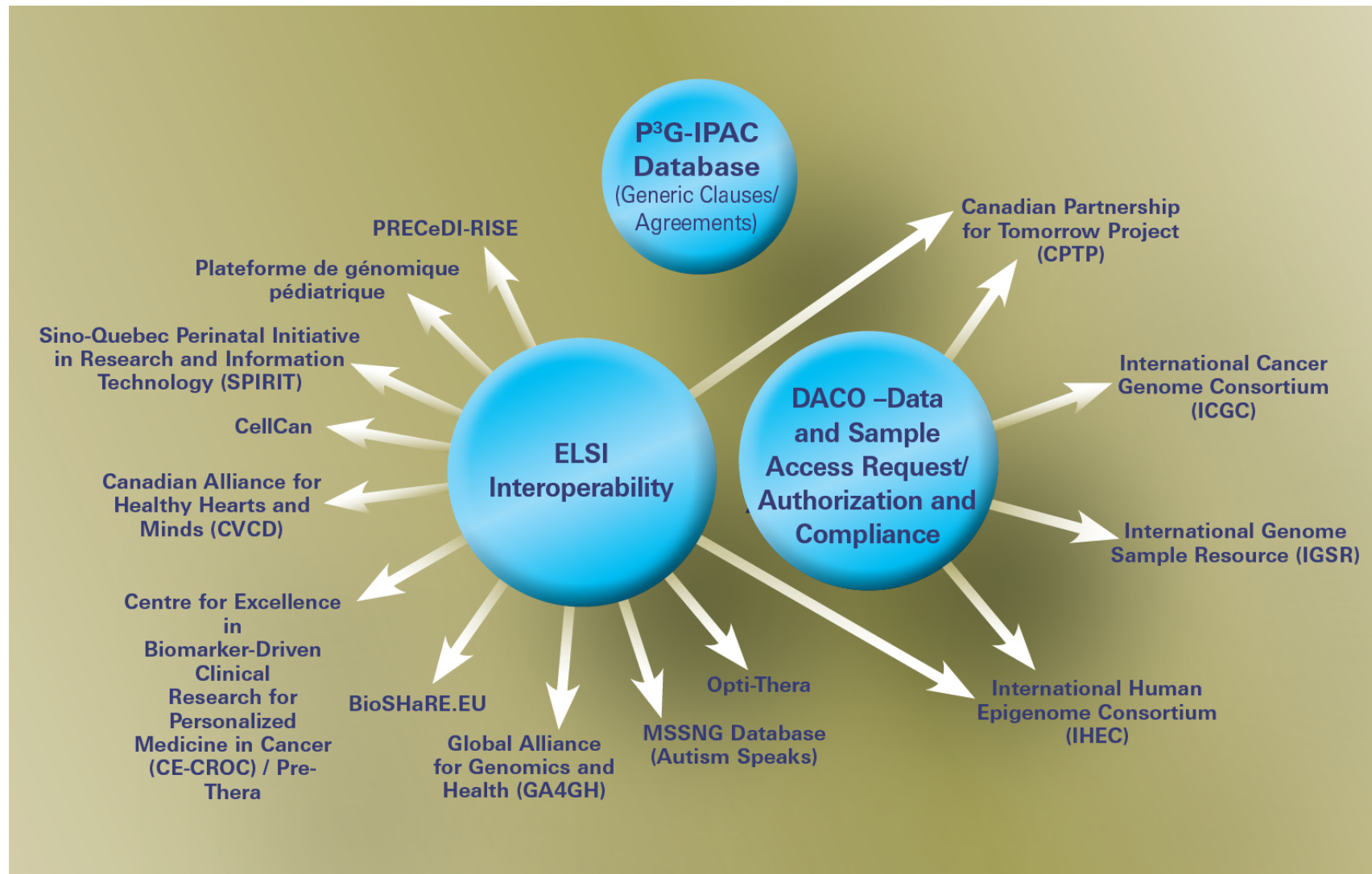
International Policy interoperability and data Access Clearinghouse (IPAC)

A one-stop service for researchers

Data/Sample Collection – ELSI Interoperability	DACO – Review of Data and Samples Access Request/ Authorization and Compliance	ELSI Clauses/ Agreements Database
Validate whether studies can work together (e.g. consent; confidentiality; etc.); If not, create tools.	Authorize studies to access controlled databases (e.g. ethics approval/waiver; institutional sign off; etc.).	Open access resource allowing users to search and select models of clauses that best suit their needs.

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Consent Tools for GA4GH

A. Legacy Consent and International Data Sharing.

B. Clauses for International Data Sharing.

C. Generic International Data Sharing Consent Form (Prospective).

A. Legacy Consent

Does original consent cover new projects? Considerations:
1. Was international data sharing foreseen?
2. Was access to the medical record foreseen?
3. Was genetic/genomic research foreseen?
4. Was potential commercialization foreseen?

Int'l sharing of Legacy Collections may require:

- **Re-consent**, or
- **Re-contact** with notification and opt-out, or
- **Waiver** from competent body

A. Legacy Consent (cont'd)

- Research Ethics Board or comparable independent bodies must have the authority to waive consent for research use(s) of data and samples already collected when:

  - The research is minimal risk;
  - The data and samples are necessary for research;
  - Researchers take appropriate measures to protect privacy and confidentiality; and,
  - It is impossible or impracticable to obtain consent.

B. Clauses for Int`l Data Sharing

1. Preamble: This project is guided by the *Framework*
2. Participate in International Data Sharing Research
3. Privacy and Security Safeguards
4. Storage (Duration)
5. Withdrawal

C. Generic International Data Sharing Consent Form

- http://genomicsandhealth.org/files/public/GA%20P3G-IPAC%20Consent%20Tools.pdf

- A one-size fits all is not possible given biobank diversity

- Broad Consent; Specific; and Dynamic Consent

- Governance: degree and scope should be proportionate to the size and purposes of the biobank.