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# Navigating Differences to Achieve Common Goals

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National Human Genome Research Institute

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National Human Genome  
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The **Forefront**  
of **Genomics**<sup>®</sup>

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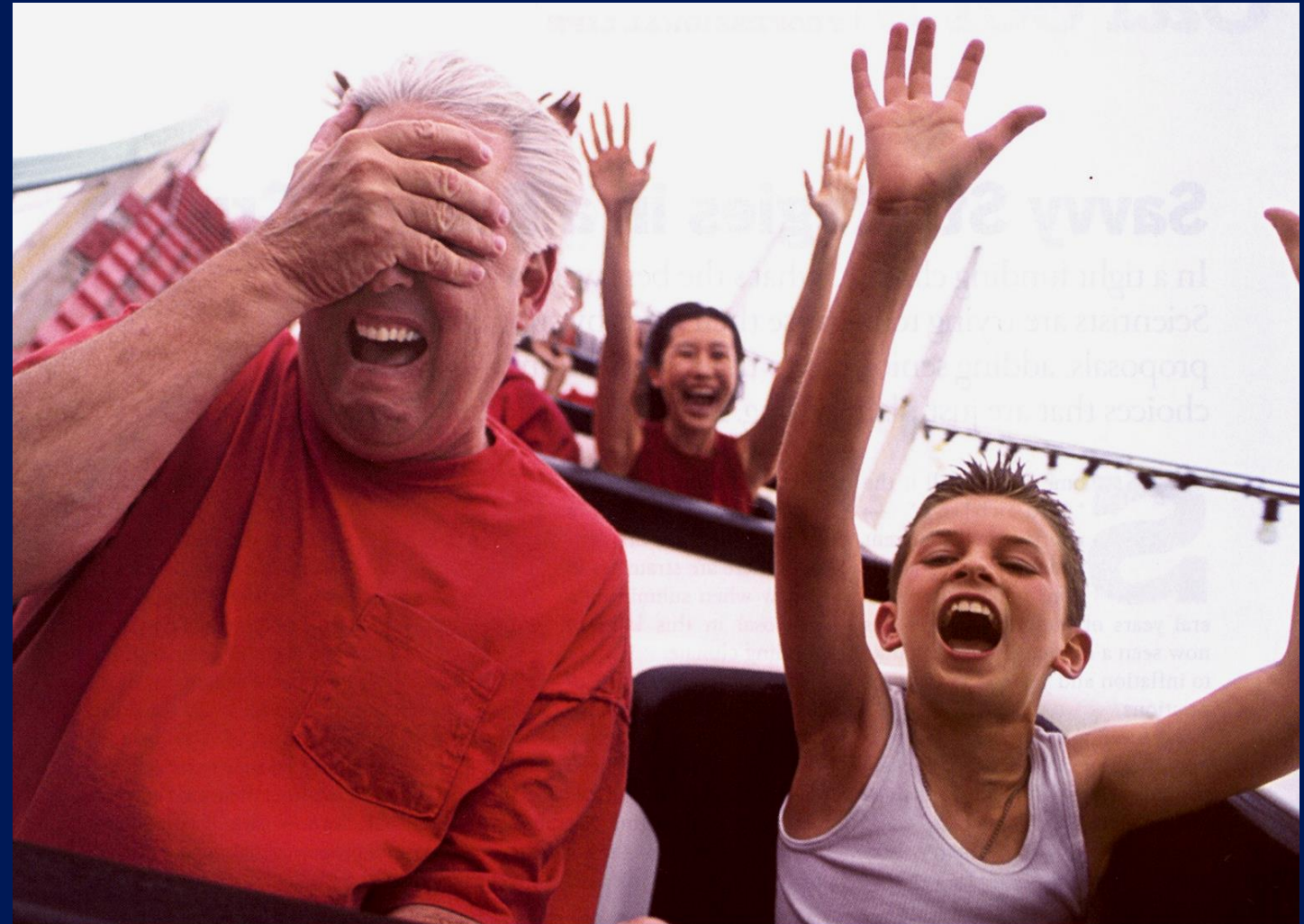
# What We Know

- Risks are not static or always quantifiable
- Respecting consent is fundamental, but not enough
- Privacy is not absolute, but paramount
- Data security procedures won't be perfect, so they must be responsive

# Need to Accommodate Differences

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Values  
Risk tolerance  
Privacy perspectives  
Cultures



# A Foundation for Cohort Participation

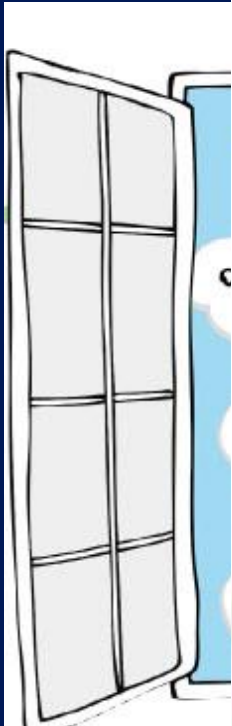
trust

noun \ 'trəst \

- 1 a** : assurance, education reliance on the character, ability, strength, or truth of ~~so (n) or a charge or duty~~ imposed in faith or confidence or as a ~~condition of some relationship~~ pledges something committed or entrusted to one to be used or cared for in the interest of another

# Building and Sustaining Trust

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Info

C

On-going communication

tions

cedures

Regulatory Oversight

# Look to Available Frameworks

## 1. Privacy & Trust Principles, PMI, USA

- Governance **Purpose:**
- Transparency
- Respecting Participant Preferences
- Reciprocity
- Data Sharing, Access, and Use
- Data Quality and Integrity



# Look to Available Frameworks

## 2. Framework for Responsible Sharing, GA4GH

### *Purpose:*

To provide a principled and practical framework for responsible sharing of genomic and health-related data

### *Foundational Principles:*

Respect Individuals, Families, Communities

Advance Research and Scientific Knowledge

Promote Health, Wellbeing and the Fair Distribution of Benefits

Foster Trust, Integrity and Reciprocity



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# Look to Available Frameworks (cont.)

## GA4GH Framework Core Elements:

- Transparency
- Accountability
- Data Quality & Security
- Privacy, Data Protection & Confidentiality
- Risk-Benefit Analysis
- Recognition & Attribution
- Sustainability
- Education & Training
- Accessibility & Dissemination



Informed  
Consent





# Informed Consent Policy Discussions



## GA4GH Consent Policy – Basic Principles

- Consent is an open, communicative and, ideally, continuing relationship.
- There is an intention to share data across clinical/research groups and/or jurisdictions and national borders with appropriate approvals in place.
- Plans for data sharing should be transparent, understandable and accessible.
- 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.
- Data users and data producers will abide by applicable regulations and ethical norms when seeking and conducting international data sharing.

Provides best practices

# Informed Consent Tools



(1) Legacy Consent and International Data Sharing, (2) a Generic International Data Sharing, and (3) a Generic International Data Sharing

**P3G-IPAC Generic Consent Clauses for International Genomics Research**

Source: *JLME* Vol 43, Issue 4, pp. 690 - 702

<b>Storage</b>	“Data will be kept for a period of [number of years/identify permittee [or other oversight body] decides otherwise. Should data be kept longer than [number of years/identify permittee [or other oversight body] decides otherwise, it will be destroyed.]”
<b>Privacy Safeguards</b>	“Your data will be stored in online secure databases (i.e., a server) that meet international security and safety standards. Your data will be shared around the world. In order to keep your information confidential, numerous safeguards will be implemented. In particular: Personal identifiers will be removed (i.e., name/date of birth); • Your personal details will be kept separate; • Your data will be coded; and • Stringent security measures will prevent unauthorized access to your data.”
<b>International Sharing</b>	“Data will be made available to other researchers around the world for use in medical research in universities, hospitals, non-profit groups, and other organizations, after approval. All researchers will have to respect the laws and ethical guidelines that apply to biomedical research.”
<b>Access Governance</b>	“Researchers who wish to access the database will be required to apply to [Name Data Access Office] who will review their request and notify them of the outcome.”
<b>Withdrawal</b>	You can withdraw your consent at any time. If you do, your data will be removed from the database and destroyed. You can also withdraw your consent from any research that is currently using your data.



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**Informed Consent for Genomics Research**

**The Informed Consent Resource**

[Consent Form Samples](#)

[Elements of the Consent Form](#)

[Genome Research Considerations](#)

[Glossary](#)

[Resources and Educational Tools](#)



National Human Genome Research Institute

<https://www.genome.gov/informedconsent/>

DATA SHARING LEXICON

Version 1.0, 15 March 2016

**Global Alliance for Genomics & Health**  
**Data Sharing Lexicon**

[https://www.ga4gh.org/docs/ga4ghtoolkit/regulatoryandethics/GA4GH\\_Data\\_Sharing\\_Lexicon\\_Mar15.pdf](https://www.ga4gh.org/docs/ga4ghtoolkit/regulatoryandethics/GA4GH_Data_Sharing_Lexicon_Mar15.pdf)

# The Privacy Conundrum

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# The Privacy Conundrum

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# Privacy Policy Discussions



Global Alliance  
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PRIVACY AND SECURITY POLICY

Version: 26 May 2015

## Global Alliance for Genomics and Health: Privacy and Security Policy

*“Privacy is a fundamental value of human societies...Its protection also promotes other core human values. However, privacy is not an absolute right. Privacy protection involves the delicate balance of considerations at individual, familial, and societal levels...”*

# GA4GH Privacy Best Practices



- Primary Duty of Data Privacy Protection
- Consent
- Ensuring Proportionate Safeguards
- Re-identification
- Data Quality
- Data Disclosure & Publication
- Collection & Sustainability
- Access
- Data Breach
- Accountability
- Transparency
- Complaints or Inquiries
- Vulnerable Populations

# Putting the Pieces Together

## ■ Science

- Capacity to analyze and interrogate massive data sets
- Powerful, innovative methodology development
- Standards and interoperability for big data

## ■ Policy & Regulations

- Ethical principles & values
- Legal frameworks
- Consistency, coordination and clear requirements

## ■ Governance

- Vision and collaboration
- Clear responsibilities
- Accountability



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**Thank You!**  
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