Clinical Trial Data Sharing: Openness at the Cost of Privacy?

27 October 2016
IRB Research Ethics Forum: Data Sharing and Open-Science

Adrian Thorogood
adrian.thorogood@mcgill.ca
Academic Associate, Centre of Genomics and Policy
Regulatory and Ethics Working Group Coordinator, Global Alliance for Genomics and Health
Data Sharing Policies

Mandatory?
Encouraged?
Voluntary?
Institute of Medicine – Data Sharing Policy

REBs:

• “provide guidance and templates for informed consent for participants that enable responsible data sharing;
• “consider data sharing plans when assessing the benefits and risks of clinical trials; and
• “adopt protections for participants as recommended by this committee and the emerging best practices of clinical trial data sharing initiatives.”
Openness v.s. Anonymity?

Privacy in context: richer data, wider access, linkage possibilities, longer data life cycle.
Openness v.s. Confidentiality?

Be prepared for the big genome leak
It is only a matter of time until idealism sees the release of confidential genetic data on study participants, says Steven E. Brenner.

THE QUESTION IS NOT HOW TO PREVENT A LEAK BUT HOW TO MITIGATE THE FALL-OUT.
Openness v.s. Privacy

- **Technology:** the challenge cannot be overcome only with technical solutions

Openness v.s. Privacy

- **Consent:** Individuals’ willingness to be open about their data does not obviate responsibility for reducing privacy risks

Privacy Norms - International Variation

**Governance Framework**
- Specific Law or Articles
- Data protection law
- Specific Guidelines
- Genetic-specific restrictions
- Government approval/license required

**Consent, Privacy and Security Issues**
- Broad consent
- Int’l sharing
- De-identification, preferred or required
- Specific security req’ts
  - *most have general req’ts
- Prohibited

**Countries**
- Canada
- China
- France
- Germany
- India
- USA
  - New rules proposed
- UK
Cooperation Between Stakeholders

Data Producers (Enable Access/Use)

Data Users (Responsible Use)

INFRASTRUCTURE

Trust?

Accountability?
Cooperation Between Stakeholders

Data Producers
(Enable Access/Use)

Data Users
(Responsible Use)

REB
Assess Sharing Plan
Consent Design
Data Release

REB
Oversight
2ndary Use

INFRASTRUCTURE
Ensure Governance is Sufficient

Institution / REB
Researcher / Sponsor
Repository / Data Access Committee
Institution / REB (Secondary Use)
REBs: Should you hold Researchers Accountable for *not* Sharing?
Ensure Governance is Proportionate
Conditions of Access and Use

- Consent design
- Consent acquisition
- Legal/policy requirements
- Institution & researcher requirements

? Interpretation?

? Precision?

? Clarity?

Potential Uses

(Anthony Brookes)
Policy Harmonization

Framework for Responsible Sharing of Genomic and Health-Related Data

- Consent
- Consent Clauses and Templates
- Consent Codes
- Automatable Consent

- Lexicon
- Privacy & Security
- Accountability
- Ethics Review Equivalency

Specific Policies emphasizing Proportionate Governance
Acknowledgments

CGP:
David McLauchlan
Prof Bartha M Knoppers

adrian.thorogood@genomicsandhealth.org