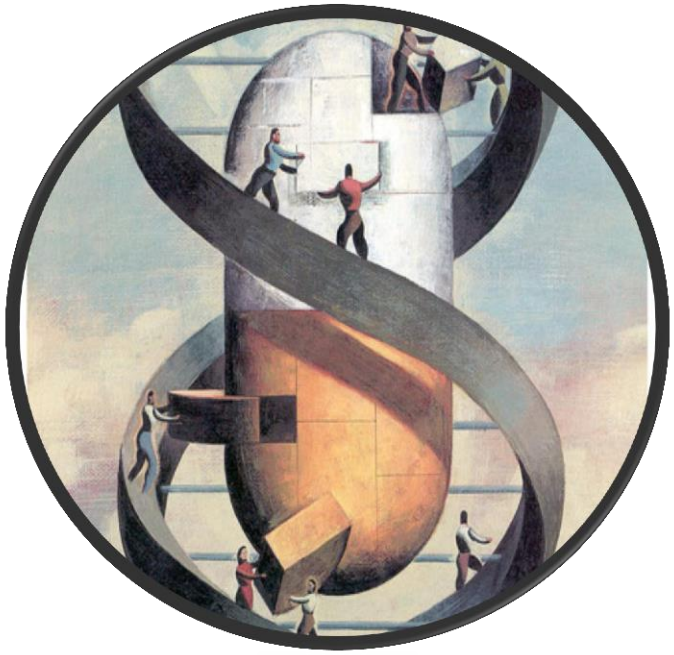
Controlled Data Access for Precision Medicine: An Acceptable Trade-off?

Yann Joly, Ph.D.

McGill

CGP Centre of Genomics and Policy
Centre de génomique et politiques

Outline



- Context
- Controlled Access
- Open Consent
- Registered Access
- Privacy-Enhancing Technologies
- Discussion

Context

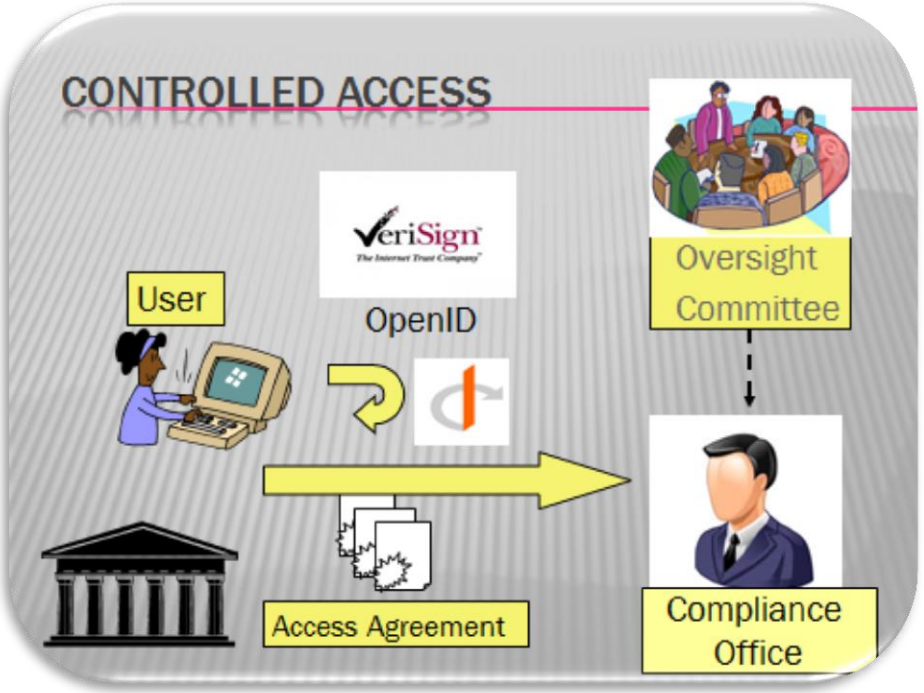
- Context: Personalized Medicine
  - Genetic data, clinical data, metadata & biopsies
  - Longitudinal follow-up, incidental findings and return of results
  - Protection of samples and data via IT security tools, good practices and coding systems

Context

- Personal data: Sharing and privacy protection
  - UNESCO, *International Declaration on Human Genetic Data*, 16 October 2003
  - Toronto International Data Release Workshop, *Prepublication data sharing (Toronto Statement)*, 2009
  - GA4GH, *Framework for Responsible Sharing of Genomic and Health-Related Data*, (2014)

Controlled Access

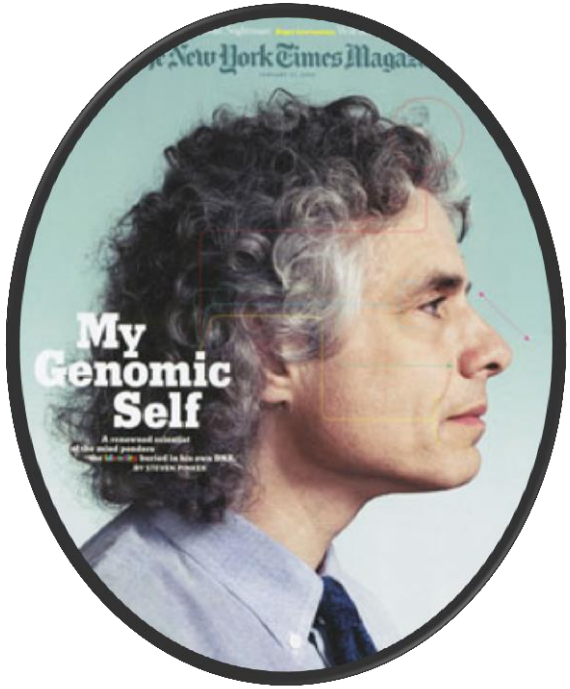
- Confirm professional status
- Summarize project
- Agree to specific conditions (ex. no re-identification of participants)
- Data Access Committee (DAC)



Controlled Access

- Over regulation?
- Unpopular with scientific community
- Low quality of the data?

Open Consent



- Mostly considered in UK and US
- Consent to unrestricted data disclosure and secondary use
- No promise of anonymity, privacy or confidentiality of participants
- Data can still be coded or anonymized

Open Consent

- No particular effort made to protect privacy/security of participants' data
- Unlikely to be permitted by the current laws of many European and Asian countries
- Could promote inequalities in access to PM research for participants unwilling to subscribe to this approach

Registered Access

- Approach situated between ‘open access’ and ‘controlled access’
- Assessment mainly concerned with the qualifications of applicants
- Conditional upon a pre-assessment of the likely ethical and legal risks of data misuse

Registered Access

- Simpler
- Less expensive (automatization)
- Model still in its early pilot phase in limited number of projects

Privacy-enhancing technologies for data analysis

Good IT security tools and practices

- Firewalls
- Virus patches
- Encryption
- Data de-identification
- Authentication schemes

Privacy-enhancing technologies for data analysis

- Securely pool individual participant data from multiple studies to answer specific research questions
- Securely perform meta-analyses of aggregate data derived from study-specific analyses.

Privacy-enhancing technologies for data analysis

- Early pilot phase
- Associated with significant legal, financial and political challenges
- Require broad users base ready to adopt harmonized disease and phenotype ontologies and to use a common analysis model

Discussion

- No model capable of replacing controlled access in the near future
- Registered access will play an increasingly important role in the next few years
- Privacy concerns and expectations of research participants are likely to evolve in the coming years as the implications of data-intensive science and computerization of health data are better understood

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