

Genetic Research Databases: Ethics and Governance

William W. Lowrance, PhD

lowrance@iprolink.ch

P3G Meeting
Manchester
15 December 2003

*Three topics in 15 minutes...**

- A few generic issues
- The UK Biobank Ethics and Governance Framework
- A few worries

** ...and just before lunch, as well*

A personal concern, expressed quietly to this group of colleagues

The development of large, complex, multipurpose data-and-tissue banks for research amounts to an exciting scientific sea-change.

This demands a matching ethico-legal sea change.

But it is not clear that society and its ethical and legal structures are well prepared yet to make or cope with this change.

A few generic issues

- Ethical recruitment, and sustaining involvement
- Legitimate consent/ permission/ authorization to open-ended, unpredictable, long-term use of data and tissues
- Safeguards that are robust enough to sustain the broad consent
- Right to withdraw, and the handling of withdrawal
- Handling of identifiability and key-coding
- What to tell participants about themselves
- Terms of access and use: openness? exclusiveness? IP?
- Effective governance
- International dimensions.

A great source of difficulty – the array of intersecting societal controls

Healthcare licensing, accreditation, and confidentiality guidance

Public health laws (disease registries, regulation of healthcare products, health statistics, mental health, venereal disease...)

Research ethics guidelines and regulations (Helsinki, CIOMS, HUGO, US Common Rule, UK MRC...)

Tissue guidelines and laws (Swedish Biobanks Act, US NBAC, CIHR stem cell guidelines...)

Exempting laws and regulations (Iceland Health Sector Database Act, Sec. 60 of UK H&SC Act, US Certificates of Confidentiality...)

Privacy-protection regimens (EU Data Protection Directive, national and provincial data-protection acts, US HIPAA Privacy Rule...)

UK Biobank Framework – 1

- An Ethics and Governance Framework was prepared by the Funders, with extensive involvement of an Interim Advisory Group
- Purpose: *to enable the conduct of ethical science*
- Confirms UK Biobank as the *custodian and steward* of the data and sample collections
- Addresses relationships with participants, research users, and society
- Is high-level, comprehensive, public, and expected to evolve, and is a governance document against which actions will be keyed.

(www.ukbiobank.ac.uk)

UK Biobank Framework – 2

- Deals with UK Biobank as a *resource* (multiple users, multiple purposes, diverse data, tissues, linking to other databases, very long-term...)
- Covers use of data after loss of mental capacity, or death
- Construes consent as *consent to participate in UK Biobank, with all that that involves (spelt out)*
- Affirms that *consent is consent, until withdrawn* (no re-consenting)
- Strongly defends voluntariness and the right to withdraw
- Requires that participants be either in or not in UK Biobank (impossible to pick-and-choose research users or purposes)
- Promises safeguards and careful protection of confidentiality.

UK Biobank Framework – 3

- Predicates research access on passing (all):
 - Scientific peer review
 - UK Biobank approval of purposes and auspices
 - NHS Multi-centre Research Ethics Committee review
- Allows only provision of anonymised data for research (but, details of anonymisation?)
- Grants no exclusive access, as a general rule
- Requires broad societal sharing of benefits
- Commits to active engagement with participants and society
- Establishes robust governance, including an independent Ethics and Governance Council.

The governance challenge

The challenge is to have principled governance that:

- firmly oversees purposes, budgets, and operations
- fits with established ethics and governance structures
- directs and holds *management* accountable
- guides and holds *researchers* accountable (internal, external, and maybe very external)
- is genuinely responsive to various publics' concerns but does not get hijacked by special interests
- continually assures participants, publics, and the financial supporters that all is well.

Some governance issues

- Privacy and data protection
- Tissue protection
- Research-subjects protection
- Fiduciary control
- Legislative foundations?
- Monitoring and auditing
- Legal sanctions against abuse
- Extension of responsibilities across national or other legal jurisdictions as necessary

UK Biobank – Governance structures

- Board of Directors (Sir Alan Langlands, chair)
- Science Committee (Professor John Bell, chair)
- Ethics and Governance Council (*being established*)
- NHS research governance, including Multi-centre Research Ethics Committee review

UK Biobank – Ethics and Governance Council

- Established by MRC and Wellcome Trust, set up in such a way as to be, and be seen as being, *competent* and *independent*
- To serve as a "mirror" for UK Biobank, and:
 - Act as guardian of the Ethics and Governance Framework
 - Advise the Board and report publicly on the conformance of UK Biobank's activities with the Framework and the interests of participants and the public

A few worries...

- Is it proper to cast these initiatives as "genetic" projects?
- Will it be possible to reconcile the intersecting, and sometimes conflicting, societal controls?
- Complications from the interlinking of diverse databases?
- Participant and and IP interests in human materials?
- Access by police, courts, insurers, banks, divorce detectives?
- Interests of relatives?
- Human-subjects and data-protection issues when data or materials are transferred internationally: legality? stances on anonymization? enforceability of commitments?