global biobank week

Towards Harmony in Biobanking

Stockholm, Sweden | September 13-15, 2017

Broad Consent for Future Research: International Perspectives

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Reasons for this study

- U.S. Common Rule Amendments (2017/2018) allow broad consent for secondary research of samples and data.
- 2 key elements of broad consent are initial consent and oversight of researcher access.
- Can the U.S. learn from international experience?

International policies

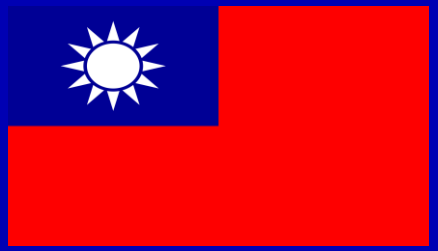
- Bartha Knoppers and I studied regulation of biobanking in 20 countries (2014-2016).
- 12/20 countries used broad consent.
- We selected 5 diverse countries to explore some specifics of broad consent.
  - Canada (Québec)
  - United Kingdom
  - Taiwan
  - Israel
  - Nigeria

Population biobanks

- Canada (Québec – CARTaGENE)
  - 40,000 representative individuals (age 35-69).
  - Initial consent is for 50 years.

- United Kingdom (UK Biobank)
  - 500,000 participants.
  - Uses 5-year renewal consent.

- Taiwan
  - Goal of 200,000 participants.
  - Human Biobank Management Act of 2012.



Federated biobanks

- Israel (Israel Collaborative Biorepository for Research)
  - National federation of 4 leading biobanks.
  - Genetic research requires additional level of approval.

- Nigeria (H3Africa international federation)
  - Broad consent must consider the nature of the project and the type of sharing contemplated.

Initial consent

U.S. Common Rule Amendments actually have detailed provisions for initial consent:

1. A general description of the types of research that may be conducted.
2. A description of the specimens or data that might be used in the research.
3. A description of the time period during which the specimens and data might be stored or used.

4. A statement that the participants might not be informed of the details of any research that might be conducted.
5. A statement that research results might not be disclosed to the participant.
6. Contact information for questions and in the event of research-related harm.

General provisions for informed consent

1. A statement that a participant's biospecimens (even if identifiers are removed) may be used for commercial profit-making activities.

2. A statement indicating whether clinically relevant results will be returned and under what conditions.

3. For research involving biospecimens, whether the research will or might include whole genome sequencing.

4. A description of the specimens or data that might be used in the research, whether sharing might occur, and the types of institutions or researchers that might conduct the research.

Researcher access

- Canada (CARTAaGENE)
  - Independent Samples and Data Access Committee
  - Enriched data must be returned for future use
  - Samples and data are re-coded for every access request
- UK
  - Biobank Access Subcommittee
  - All samples must be non-identifiable to the researchers
- Taiwan
  - REC oversees
  - Personal information is encrypted and independently administered
  - Participants can sign consent to be re-contacted by biobank

- Israel
  - Ministry of Health and institutional ethics committees
  - National Ethics Committee (Helsinki Committee)
  - Most research is subject to self-regulation and self-reporting
- Nigeria
  - Internal access (H3Africa) go directly to PI who generated data
  - External access uses Data and Biospecimen Access Committee
  - For 1st 3 years after collection, samples are only available to researchers in Africa and their collaborators

Conclusions

1. Countries vary widely in broad consent.
2. Broad consent is evolving.
3. Broad consent has been well received.
4. No reports of misuse or breaches.
5. U.S. is outlier in permitting minimal deidentification of extant samples and research without any consent, notice, or external oversight.
6. “Limited IRB review” should be rigorous.

Collaborators

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