TRUSTED GOVERNANCE & BIOBANK RESEARCH

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Trusted Governance in Research

"Governance" refers to a regime established to engender trust, to organize oversight and to ensure institutional accountability.

Research contexts:

- biorepositories (biobanks)
- electronic health information

1st Generation

Researchers have been using stored biospecimens and associated clinical or phenotypical data for some time – until recently:

- bioresource usually created by single investigators or research teams
- created for retrospective analysis of specific diseases
- samples typically collected in the context of a clinical relationship
- anonymization as primary means to protect privacy and limit institutional oversight (exempt from review)

“Next Generation” Biorepositiory Research

- National research initiatives such as the CTSA aim to create large networks of collaborating institutions and large data sets, resulting in increasing distance between researcher and participant
- Public health research – large numbers of participants followed prospectively
- Emerging areas of research, such as pharmacogenetics, require access to large pools participants, which are of greatest scientific value when linked to identifiable personal information.

Conceptual Challenges of Next Gen

- Disutility of anonymization
  - no recontact
  - clinical data not current
  - no withdrawal possible
  - possibility of longitudinal data collection foreclosed
  - thin assurances of anonymity
- Individualist orientation v. collective goods – laws, policies and practices designed to protect individuals do not fit goals of biobank research
- Samples and data are collected for future research uses that may not be formulated yet

In sum

Conventional approaches that allocate decision making to donors, or seek to protect them via limited data sets made available only to particular investigators are tools that likely will not suffice in the next generation biorepositories context.

Next Gen Ethical Challenges

- Privacy Protections
- Informed Consent
- Data Sharing and Stewardship
- Return of Research Results
- Incidental Clinical Findings

Varieties of Consent

- One-time consent for specific research use
- Secondary research use consistent with the original consent (e.g., any cancer research but not Alzheimer's)
- “Broad” consent – secondary use consistent with the type of data stored, e.g., stored clinical biospecimens could be used in non-clinical research - say, genetic studies - and consent form does not deny such use
- “Blanket” consent” – allows unrestricted research, i.e., blankets all possibilities [arguably lacks *informed* element]
- “Tiered” consent: requires an informatics system capable of tracking the levels of consent

Problems with Blanket Consent

- No basis for establishing congruence between donor/participant values and use of their samples in research; potential psycho-social harms
- No mechanism of accountability to donors; non-welfare risk of failure to protect the moral significance of the donation
- Consent is disassociated from information

*Example: Tiered Consent

- ☐ My tissue may be kept for use in research to learn about, prevent, or treat cancer.
- ☐ My tissue may be kept for use in secondary research to learn about, prevent, or treat other health problems; e.g., diabetes, Alzheimer's disease, heart disease, etc.
- ☐ My tissue may be associated with my medical record and history.
- ☐ I am willing to be contacted about future research studies.

*NCI 2011 Best Practices

Trusted/Trustee Consent

- Participant consents to a specific form of research oversight, a set of institutional arrangements rather than to specific research study
- Participant delegates secondary use decisions, decisions about recontact, etc. to designated Trustee/Trusted broker an independent board/entity with broad representation - especially participant representation - whose primary role is to align interests with participants.
- Trustee monitors potential research risks and developments, and notifies participants as appropriate.
- Trustee participates, with other institutional actors such as IRB, Privacy Office, etc. in developing response to scientific, technical and policy developments.

Right to Informed Donation

In support of Trusted Consent, certain kinds of information should be publicly available to prospective donors:

- governance structures, policies and administrative practices
- general information about previous and current research involving bio bank should be publicly available to prospective donors/patients/participants, including social implications and controversial aspects
- information regarding withdrawal (destruction of samples and/or links)
- information regarding modes of contact, if any, re clinically significant research findings

Precedents

- Hospital Ethics Committees
- IRBs and Research Ethics Committees
- Disease-specific research enterprises
- Trustees of Charitable Trusts
- Federal Reserve System

The idea is that structures of accountability with (1) appropriate advisory representation and (2) transparent policies and procedures can together constitute an organization that allows for sufficient confidence in its long-term behavior (in effect, a moral personality) that is worthy of trust.

Models

- “Trusted broker” type – disinterested, balances interests of stakeholders (research participants/donors, investigators, institution/research administration, local community, scientific enterprise, future generations, etc.) but is
- Agent/Principal relationships - delegation, assumes congruent interests, analogous to health care surrogate

Advantages of Trusted Governance

- flexibility, adaptability
- mechanism to address community-specific needs via meaningful incorporation of relevant values and interests, community consultation and power-sharing
- establishment of strong relationships of trust via governance structures which are perceived to be worthy of trust (transparency, fiduciary orientation, accountability, etc.)

Relationship to Other Institutional Actors

- Varies by institutional culture
- Miami CTSI Research Ethics program has responsibility for making recommendations; we envision providing advice on best practices to other UM actors such as IRB, Research Admin, Compliance and Risk Management, Privacy office, management, etc., where regulations are vague, contradictory or non-existent or where groundbreaking approaches are under consideration.

Resources

Research Ethics Consultation Service (RECS)/University of Miami Ethics Programs

http://www.miami.edu/index.php/ethics/projects/recs/

Research Ethics - Miami Clinical and Translational Science Institute

http://miamictsi.org/about/ctsi-programs/research-ethics