

# Biobanking, Stored Specimens, and Data 2: Risks, Benefits, & Custodianship

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# Risks and benefits

1. Risks to participants and communities
2. Benefits for participants and communities
3. International collaborative research

# Risks to participants & communities

# Typical risks for participants

- From obtaining samples, e.g. via blood draw
- From misuse of samples, e.g. disclosure of private information



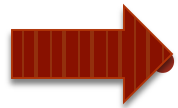
# Standard privacy protections

- Samples and paper records in locked storage
- Electronic data encrypted or passcode protected
- Identifiers removed
- Access granted only to individuals who require it

... etc.

# Minimal risk?

- Compare with risks of daily life:
  - Short car journey: 1 in 1000,000 chance of dying
  - Game of football: 1 in 10,000 chance of ligament tear
- Are comparable harms caused by research on stored specimens and data?
  - Very few serious harms reported despite hundreds of millions of genetic research tests



Typically minimal risk

# Special populations

- Risks associated with breach of confidentiality higher, e.g.
  - Stigmatized health condition
  - Illegal behavior
- Dissemination of results could lead to harms, e.g.
  - Liable to be misinterpreted
  - May reinforce stigma or stereotypes

# A “gene for” aggression

- A correlation between a MAO-A gene variant and anti-social behavior was identified in Caucasian men
- Described as a “warrior” gene
- Researchers presented results of research on Maori (indigenous New Zealand) population:

“Obviously, this means they are going to be more aggressive and violent and more likely to get involved in risk-taking behavior like gambling... it has implications suggesting links with criminality among Maori people.”



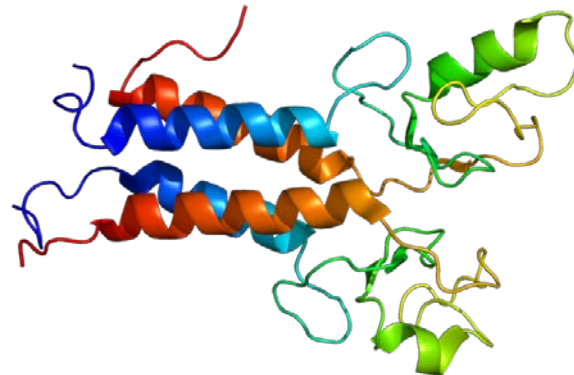
# Community engagement

- Active involvement of the community in planning and carrying out the research
- Advantages:
  - Identify and mitigate risks
  - Design effective consent strategies
  - Make research more responsive
  - Respect communities

# Benefits to participants & communities

# Incidental findings

- “A finding concerning an individual research participant that has potential health or reproductive importance and is discovered in the course of conducting research but is beyond the aims of the research.” (Wolf et al. 2008)
- e.g. Discover BRCA variants in breast cancer tumor samples



# Incidental findings

- Debate over exactly what findings should be returned to participants
- Near consensus that they must be clinically significant and actionable
- Researchers and biobanks should have a plan for dealing with incidental findings
- Advantage of biobanks that
  - Keep in touch with donors
  - Maintain identifiable samples

# Dissemination of research

- Treats donors as partners
- Ensures that research is valuable
- Various media can be used, e.g. newsletter, website
- But, must be appropriate to the audience, e.g. scientific abstracts and articles are usually inadequate

# International collaborative research

# International collaborative research

- Researchers from two or more countries
- Frequently collecting specimens and data in multiple countries
- Frequently involves researchers from high-income countries and low- or middle-income countries

# Ethical issues

- “[B]lood samples were extracted from some members of the Hagahai, a small group of hunter-gatherers living in an inaccessible mountain range in Papua New Guinea. The researcher involved told the group that she wanted to see a 'binitang' -- an insect -- in their blood. Analysis of these blood samples revealed existence of antibodies to a variant of the HTLV-I leukaemia virus. This was used to produce an immortal cell line, which was the basis for a patent application...”

(Thambisetty 2002)



# Key issues

- Who has access to samples and data to conduct research?
- How should benefits from the research be distributed?

# Access: establishing biobanks

- Key questions:
  - Where will the biobank be located?
  - Who will operate the biobank?
- Affects who uses the biobank, what research is conducted, who gets what benefits, what regulations apply, etc.

# Access: mechanics

- Typically data access agreements and material transfer agreements (MTAs) between biobanks and researchers and/or institutions
- Limit uses and users
- Extend the responsibilities of the biobank to recipients of samples and data



# The content of agreements: points to consider

- Specify uses and users
- Specify responsibility for security of samples and data
- Specify what review is required
- State that researchers will not attempt to re-identify de-identified samples and data

# Terms of access: points to consider

- Transfer across borders
- Which institutions and researchers should be allowed access
- Which research projects should be supported
- Benefit-sharing with communities

# Terms of access: guiding principles

- Reciprocity for those who provide samples and maintain the biobank
- Maximizing social value of the samples and data

# Access disparities

- Perceived disparities between HIC and LMIC scientists:
  - Authorship
  - Intellectual property
  - Decision-making power – what research is conducted

# Potential benefits

- Training of researchers and clinicians
- Development of research infrastructure
- Development of collaborative partnerships
- Economic benefits
- Health benefits



# Health benefits

- Is the research responsive to local health priorities?
- Do the results of research have the prospect of changing local health care and health policy?

... i.e. Does the research have sufficient *local social value*?

# Summary

- Substantial benefits to sharing samples and data
- Risks to *most* participants are minimal
- Researchers should plan for incidental findings and dissemination of results
- Key issue: how to operationalize biobanks to encourage research with *local* social value

# Case presentation: specimen research in an international collaborative study

# The study

- Examining the genetic basis of hereditary deafness
- Enrolling patients and family members
- Includes a blood draw and buccal swab for DNA testing
- Hundreds of genes may be linked to deafness, so hoping for large sample
  - Enrolling children and adults
  - Multiple sites and countries

# Subjects in West Africa

- The US PI has contacts in several West African countries working in schools for the deaf
- He proposes to enroll up to 500 children and family members from these schools
- Parents/guardians will give consent where available
- Headteachers will give consent for children whose parents/guardians are not available

# Samples in West Africa

- Samples from West African participants will initially be stored in-country
- Some analyses will be only West Africa-specific, but some will not
- Once collection is complete, the PI asks to store the samples in the US where he has the infrastructure and funding to maintain the collection for at least 10 years

# Discussion