Issues with Tissues

Research Compliance Office
Stanford University
What are Tissues?

- Organic material removed from a living individual
- Including biological samples

For example,

- Blood
- Saliva
- Discarded surgical tissue
- Cord Blood

Material such as cadaver tissue or autopsy specimens don’t qualify as HSR
News About Issues With Tissues

• Henrietta Lacks
• The Havasupai Tribe
• Newborn Blood Spots

Courtesy of:
Why are tissues an issue?

The Researcher’s Issue

• An important resource for biomedical discovery and education
• Even more valuable because of genetic research
• Will be discarded anyway, and will instead be put to use
Why are tissues an issue?

The Public’s Issue

People care/are concerned about:

• Ownership of specimens
• How their tissues are used
• Genetic testing and future identification
• Others profiting from their tissues
Why are tissues an issue?

The IRB’s Issue

• Consent challenges
• “Identifiability” and privacy/confidentiality
• Risk assessment
• Return of research results
• Data sharing
Tissue Banking

Intent is to collect and store tissues for future research and distribute to multiple users for multiple purposes.

Bank has established rules for collecting, processing, storing, and distributing (IRB protocol)
Tissue Collection

Collected for a specific protocol with uses limited to that protocol

May or may not have a plan for storage or retention

No plans for distribution; not prohibited

Reference:
“Stanford University IRB Guidance On Data and Tissue Repositories”
Issue: Identifiability

• **Common Rule**
  – Identity of the person is or *may readily* be ascertained by the investigator or associated with the information

• **HIPAA regulations**
  – 18 identifiers listed, e.g.,
    • Name, SSN, medical record #
    • Zip codes, partial zip codes, or other geo-codes for populations below 20,000
    • Dates – not just of birth, but procedure, admittance

• **Can have DIRECT identifiers and INDIRECT identifiers**
Direct Identifiers

For example:

• Name/Initials
• Telephone/fax numbers
• Email, web/IP addresses
• VIN and license plate #’s
• Facial photograph or other identifying image
• Audiotapes
• Relative’s names
Indirect Identifiers

A combination of qualities that would make a person identifiable

- A study that looks at centenarians (people who are 100+ years old)
- A study that examines albinism
- Situations where unique and rare medical conditions are studied

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Genetics and Identifiability

A looming issue:
- Specimens carry a person's entire genome
- Genetic code is unique to each individual
- Without the match to a person’s genetic code, however, a researcher is not able to identify the individual from whom a specimen has been taken

When will this become a problem?
Risks of participation:

- Identification
- Inadvertent or inappropriate use of individually identifiable information
- Freedom of Information Act (data becomes a government record)
- Law enforcement access
- Risks to specific groups, populations, communities
- Risks related to return of research results
In Conclusion…

✅ Perspective
✅ Consent
✅ Sample Origination
✅ Identifiability
✅ Risk Assessment