



**OBBR** Office of Biorepositories  
and Biospecimen Research

## **NCI Best Practices for Biospecimen Resources**

# Ethical, Legal, and Policy Best Practices Overview and Challenges

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# Topics

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- Custodianship
- Informed Consent
- Privacy Protections
- Access to Biospecimens and Data
- Intellectual Property

# AGENDA

- Overview of the Best Practices
- Overview of the Challenges\*
- Comments re: Discontinuation

*\* Not all under the control of NCI*

# Custodianship

- Ensure specimen and data integrity
  - Within bank and recipient researchers
- Plans for retention and disposition of specimens and data
  - At completion of research use
  - In the event of Resource closure/transfer
- Identification and management of conflict of interest
- Transparent and culturally sensitive policies



# Informed Consent - 1

- Description of the bank operations
  - How data will be stored
  - How specimens can be accessed
  - Oversight of the bank
- Information about the risks and potential consequences of genetic research
- Ideally obtain consent prior to 'procedure'
- Specify commercial use potential



# Informed Consent - 2

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- Plans for release of aggregate and/or individual research results to individual, family, health care provider
- Plans for longitudinal data collection
- Plans for re-contact
  - If so, for what
- Consider tiered consent
- Arrangement for withdrawal from study
- Be aware of pediatric issues

# Privacy Protections

- Clear and transparent policies regarding how data will be held
  - Encrypted
  - Coded
- Consider a Certificate of Confidentiality
- Compliance with HIPAA
  - Privacy and Security

# Access

- Transparent set of general principles
- Scientifically sound and appropriate research design
  - Agreement to publish
- Compliance with privacy and human subject protection regulations and statutes
- System of defined levels of access privileges for Resource staff
- Charges, if any, limited to reasonable costs



# Intellectual Property

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- Consistent with NIH Research Tools and NIH Data Sharing Policies
- Biospecimen resource staff not considered a priori inventors for inventions made with biospecimens
- Biospecimen resources have no right to future IP



# CHALLENGES: Institutional

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- What does voluntary truly mean?
  - Consequences for not applying
  - Should all biospecimen resources be c/w the NCI best practices
- Logistic nightmare of dueling rules
  - Genome Wide Association Study (GWAS)
  - Local repositories



# CHALLENGES: Custodianship

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- To whom does the specimen belong?
- What is a gift?
- Expectations of donors
- The effect of court decisions
  - Very little case law – and what exists is state based
  - Courts have been particularly sensitive to the public policy implications of interfering with the biomedical research process



## CHALLENGES: Privacy Protections

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- HIPAA: collaboration between a variety of HIPAA entities and uncovered entities
- Future unspecified research uses
  - Disconnect between authorization (HIPAA) and informed consent (Common Rule)
- Possible overuse of Certificates of Confidentiality
  - Will their value be eroded?



## CHALLENGES: Access & IP

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- Access to specimens
  - Standardization of access rules
    - Especially in terms of scientific rigor
- Intellectual Property and Resource Sharing
  - Any exclusivity clause?
  - How does this compare to GWAS?



# CHALLENGES: Informed Consent

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- Timing of informed consent
- Who can obtain consent
- Pediatric consent
- Tiered consent
  - Logistics and understanding
- Discontinuation of participation\*

# CHALLENGES: Discontinuation

## C.2.2.9

“In the event that participation in the research study is discontinued, any remaining identifiable biospecimens and associated clinical data should be withdrawn from the biospecimen resource. *However, samples and/or clinical data that have been transferred from the biospecimen resource to investigators and research data already generated from samples need not be withdrawn.*”



## CHALLENGES: Discontinuation

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### C.2.2.9

“Instead if a biospecimen resource learns about the discontinuation of participation of a human subject, the NCI considers the biospecimen resource ethically obligated to inform investigators who received specimens from that individual.”



# CHALLENGES: Discontinuation OBBR Office of Biorepositories and Biospecimen Research

- Investigators who receive identifiable specimens should withdraw that subject from the research
- Recipient investigators could:
  - Cease using identifiable specimens
  - Remove identifiers and continue to use\*
  - Destroy identifiable specimens and data



# CHALLENGES: Discontinuation OBBR Office of Biorepositories and Biospecimen Research

Places unreasonable onus on  
investigators



# CHALLENGES: Discontinuation

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- Expectation that recipient investigator withdraw specific specimens and data.
  - Does this mean cessation of further use?
  - Does this mean destruction of any research data created using these specimens?



# CHALLENGES: Discontinuation

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- **SUGGEST:** investigators be allowed to continue to use specimens and data already received
  - Such plans should be described in the informed consent by stating that, withdrawal from participation means that:
    - Specimens and data will be withdrawn from the Biospecimen Resource
    - Specimens provided to recipient researchers will not be withdrawn. Recipient researchers will be able to continue research with these specimens



# CHALLENGES: Discontinuation

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- Removal of identifiers renders the specimen not a human subject
  - If the specimen was obtained for research purposes pursuant to informed consent
    - *If a person withdraws consent, seems that the consent covers both the specimen AND the data*
    - De-identification should only be permitted if specifically described in the initial consent

# Summary

- Tissue Banking is an invaluable resource for biomedical research
- The logistics of tissue banking are daunting
- NCI deserves kudos for their leadership