Expanding the Ethical, Legal & Policy Recommendations in the *National Cancer Institute Best Practices for Biospecimen Resources*

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What is a Biospecimen Resource?

NCI defines a a biospecimen resource as a collection of human specimens and associated data for research purposes, the physical structure where the collection is stored, and all relevant processes and policies. Biospecimen resources vary considerably, ranging from formal organizations to informal collections of materials in an individual researcher's freezer.

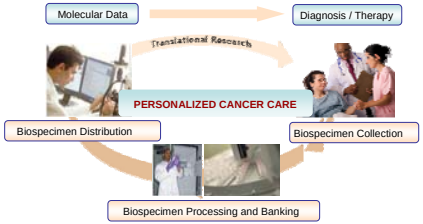
Biospecimens are Key to Personalized Medicine

High quality biospecimens are needed to:

- Understand disease mechanisms using advanced technologies
- Identify and validate new targets for detection, diagnosis, treatment, and prevention
- Develop screening tests for biomarkers associated with diseases and drug responses

Biospecimen quality and access are highly heterogeneous due to:

- Variations in informed consent and other ethical, legal and policy practices
- Differences in methods of tissue collection, preservation, and information management



NCI's Biospecimen Activities

2008
- **Symposium "Advancing Cancer Research Through Biospecimen Science"**
- **National education and outreach program about the NCI Best Practices**

2007
- **Workshop "Custodianship and Ownership Issues in Biospecimen Research"**
- **FGGs revised based on public comments and renamed NCI Best Practices for Biospecimen Resources**

2006
- **First-Generation Guidelines for NCI-Supported Biorepositories (FGGs) published in Federal Register**

2005
- **caBIG™ software tools for biorepositories developed**

2004
- **Analysis of NCI-supported biospecimen resources conducted**
- **Trans-NCI Biorepository Coordinating Committee (BCC) formed**

2003
- **Case Studies of Existing Human Tissue Repositories published**
- **National Biospecimen Network (NBN) Blueprint published**

2002
- **Internal and external review of biorepository issues begun**
- **Biospecimen resources identified as critical resources for cancer research**

Ethical, Legal, and Policy Best Practices

Objective: Unify technical, operational, ethical and legal policies and procedures for NCI-supported biospecimen resources

Presentation focus: This poster focuses only on the ethical, legal and policy recommendations contained in the NCI Best Practices

Custodianship
- Develop plans for formal and continuing custodianship of collected specimens and associated data
- Develop plans to transfer or dispose of specimens and associated data at the end of the budget period of the grant or after completion of the study objectives

Informed Consent
- Develop policies for handling specimens for which consent has been withdrawn
- State whether or not specimens may be used by commercial or for-profit companies in informed consent language
- State if identifiable or coded data will be stored
- State whether or not individual or aggregate research results will be released to the research participant

Privacy
- Document policies for maintaining privacy, including mechanisms for auditing effectiveness, enforcement measures, and training for employees
- Consider the use of certificates of confidentiality

Access
- Develop guidelines for distribution of biospecimens and data to ensure timely, equitable, and appropriate access
- Base access decisions on scientific merit
- Restrict personnel access to identifiable and/or sensitive information via data access systems with defined privilege levels
- Limit any charges for samples to cost recovery

Intellectual Property
- Use a Material Transfer Agreement (MTA) to transfer biospecimens
- Specify in MTAs that research data obtained through the use of biospecimen resource specimens and/or associated data should be made available to the research community

Expanding the NCI Best Practices for Biospecimen Resources

2007-2008 NCI Biospecimen Best Practices Forums: Bethesda, Boston, Chicago, and Seattle

Webcasts and copies of presentations from these forums are available at:
http://biospecimens.cancer.gov/practices/forum/

Forum Purpose

To educate and gather feedback from investigators, physicians, industry representatives, hospital administrators, survivors, patient advocates, and the general public about the *NCI Best Practices for Biospecimen Resources*

Forum Presentation Topics

- Overview of Technical and Operational Best Practices
- Overview of Ethical, Legal, and Policy Best Practices
- The Importance of Best Practices to Patients and Advocates
- Tools for Tracking and Accessing High-Quality Biospecimens
- Demonstration of caTissue
- Cost Recovery Models and Other Economic Issues Involved in the Implementation of the NCI Best Practices
- Assessing the Effects of Preanalytical Variables on Molecular Research

Future Outcomes

- Expanding and Adopting caBIG™ tools
- Addressing Informed Consent Issues
  - Future secondary use of biospecimens, withdrawal of consent, and consent for pediatric biospecimens
- Addressing Costs Associated with Implementing the Best Practices
  - Economic value of biospecimen resources to ensure long-term survival
  - Cost recovery mechanisms to supplement grant and contract funding

For more information, please visit:

http://biospecimens.cancer.gov

Workshop on Custodianship of Biospecimens

This workshop was convened to provide recommendations for the custodianship of human biospecimens and associated data at NCI-supported resources. The meeting brought together about 75 leaders from the academic community, private sector, patient advocacy groups, and government agencies.

Issues discussed

- Appropriate actions following withdrawal of informed consent
- Custodial obligations for biospecimen resources
- Development of contingency or legacy plans following loss of management or end of funding
- Management and disclosure of conflicts of interest
- Intellectual property rights derived from research on biospecimens
- Sharing of biospecimens and data within the research community
- Research participant access to products and benefits from biospecimen research

Workshop on the Use of Pediatric Biospecimens

This one-day workshop addressed the ethical issues involved in the storage and use of pediatric biospecimens in research. Topics included whether pediatric research participants should be re-consented for ongoing research involving their biospecimens once they obtain the age of majority. Participants included ethicists, patient advocates, legal experts, biobankers, clinicians and federal representatives.

Issues discussed

- Ethical concerns regarding use of pediatric biospecimens
- Use of pediatric biospecimens in genomic research
- Policies for the use of pediatric biospecimens appropriate for a large national biorepository
- Protections to limit research risk
- Community engagement when planning a biospecimen resource.

Future Outcomes of Workshops

- A summary of the custodianship workshop is posted on the OBBR website and a summary of the pediatric consent workshop will be posted soon
- Publications will be developed based on the findings and recommendations from both workshops
- Workshop findings will be used to derive additional recommendations for inclusion in the NCI Best Practices

Conclusion

- Periodic revision of the NCI Best Practices will occur with input from researchers, biospecimen resource managers, advocates, policymakers, and related stakeholders as new technologies, clinical practices and policies emerge
- OBBR will continue to support outreach activities and workshops to refine recommendations within the NCI Best Practices