BIOSPECIMEN BEST PRACTICES FORUM

Overview of Ethical, Legal, and Policy Best Practices
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NCI's Best Practices for Biospecimen Resources

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

Informed Consent

- **Consider allowing research participants to specify the types of research for which their specimens may be used.**
- **Develop policies for handling specimens for which consent has been withdrawn.**
- **Develop policies for obtaining consent for studies involving children.**
- **Consider special U.S. Food & Drug Administration regulations.**
- **Establish and document transparent policies to govern the retention of records and specimens.**

Access to Biospecimens and Data

- **Develop clear policies for specimen and data access.**
- **Develop clear guidelines for sample distribution and clinical data sharing (note: NCI Best Practices state that protocol-specific requirements should be met before other access is considered).**
- **Ensure that investigators have timely, equitable, and appropriate access, without undue administrative burden.**
- **Charge for samples only to recover costs.**
- **If a biospecimen resource needs to close, announce the availability of specimens for transfer.**
- **Restrict access to subjects' identities and medical, genetic, social, and personal histories via data access systems with defined privilege levels.**

Privacy Protections

- **Protect the privacy of information and follow applicable regulations.**
- **Follow documented policies on employee access to data or specimens.**
- **Provide levels of security that are appropriate to the type of biospecimen resource.**

Custodianship

- **Include plans for custodianship of collected specimens and associated data in biospecimen resource protocols.**
- **Develop plans to handle/dispose of specimens and associated data:**
  - **At end of the budget period of the grant**
  - **At completion of the specific research objectives of the study**
- **Identify and disclose financial conflicts of interest.**
- **In informed consent language, disclose that specimens may help to develop products, tests, or discoveries that may have commercial value.**

Intellectual Property

- **Use a material transfer agreement (MTA), such as the NIH Simple Letter of Agreement, to transfer materials.**
- **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.**

Ethical, Legal and Policy Consensus

- Consensus will greatly increase the acceptance of the Best Practices
- But ethical considerations, statutes, regulations and case law, and public policies still raise some of the "thorniest" issues that researchers, clinicians, patient advocates, and public policy makers confront

Two issues illustrate the interaction of ethics, law and policy

- The statutory and regulatory maze affecting biospecimens
- The not fully resolved issue of “custodianship” or “ownership” of biospecimens

NCI's Efforts to Address These Issues Include

- NCI's 2004 50-State Survey of statutes and regulations affecting biospecimens
- NCI's recent symposium on "Custodianship and Ownership Issues in Biospecimen Research"

NCI's 50-State Survey

- Laws that can be applied to the conduct of research using biospecimens exist in nearly every state
- These statutes and regulations tend to vary from state-to-state
- A state-by-state analysis may be necessary for researchers to assure compliance with all applicable state statutes and regulations

- As of 2004, nearly half the states had research exceptions that permit disclosure of medical information to researchers and 21 states allowed research use of genetic information, with conditions
- But these conditions also can vary from state to state
- This state-by-state summary must be updated annually to be serve as a useful tool for researchers

Relationship of State Statutes and Regulations to Federal Law

- Some state statutes incorporate by reference 45 C.F.R. part 46, Subpart A (the “Common Rule”) and HIPAA provisions
- When states exceed the provisions of the Common Rule, federal policies for the protection of human subjects do not preempt state laws that provide these additional protections.
- Similarly, HIPAA does not preempt state laws that impose more stringent privacy protections

Relationship of State Statutes and Regulations to NCI's *Best Practices*

- Regulations have the "force of law," federal or state agencies' best practice documents and guidances do not and thus cannot be relied on to replace an analysis of state statutes and regulations
- Courts may look to these documents when they analyze the intent of research policies, but will not use them as deciding factors in a case
- Courts rely on statutes, regulations, and case law

Custodianship and Ownership

- NCI uses the term “custodianship” rather than “ownership” of biospecimens because these issues have yet to be resolved effectively in statute, regulation or case law
- Legal challenges to ownership of biospecimens are fact specific and decisions in such a small number of cases do not yield a robust body of law

Case Law on Biospecimens from a Public Policy Perspective

- From the seminal case *Moore v. Regents of the University of California* (1990) through *Washington University v. Catalona* (2007), Courts have denied claims of tissue ownership based on common law property theories

- Courts turn to applicable federal and state statutes and regulations, but often they do not directly address the issue in the way that NCI's Best Practices do.
- Courts are particularly sensitive to the public policy implications of interfering with the research process and fear harm to biomedical research.
- To date, there is very little case law to guide the courts.

Current Options for Researchers

- Perform a methodical analysis of applicable statutes and regulations as illustrated in NCI's 50-State Survey examples
- Encourage NCI or another entity to compile and maintain a current listing of state statutes and regulations affecting all aspects of biospecimen-related research to facilitate standard state-by-state analyses
- Rely on IRB review of the informed consent process and its reflection of federal and state requirements
- Closely monitor court decisions and their reach