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
- 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- Develop policies for handling specimens for which consent has been withdrawn.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.**

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* (2006), Courts have denied claims of tissue ownership based on common law property theories.
- Courts are willing to examine breaches of informed consent – as a breach of the fiduciary relationship between doctor and patient.

- 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.

Washington University v. Catalona

- Federal District Court for the Eastern District of Missouri held that:
  - Research donors do not retain any rights to control their tissue past the donation of biological materials for medical research
  - Under Missouri law, control of property is *prima facie* evidence of ownership
  - Donation of tissue is an *inter vivos* gift with all of the elements of donation – donative intent, delivery, and acceptance

- the right to discontinue participation is not a “right”
- OHRP guidance is not legally binding
- 45 C.F.R. 46 is the standard for conducting human subjects research, therefore, there is no need to resort to international standards like the Helsinki Agreement

- Acknowledges that federal regulations require some informed consent
- Medical research can only advance if access to these materials is not thwarted by private agendas

- The Court issued a declaratory judgment that Washington University owned the biospecimens
- Case currently is under appeal
  - Oral arguments heard on December 13, 2006
  - Parties awaiting the decision of the 8th Circuit Court of Appeals

Other relevant case law from a policy perspective

- *Perry v. St. Frances Hospital* (1995)
  - informed consent is not a “contract” – only memorializes consent
- *Tilonsi v. Arizona St. Board of Regents*
  - Havasupai tribe members’ blood samples

How Would Courts Treat NCI's Best Practices for Biospecimen Resources?

- As a "policy statement" – it is not a regulation
  - Would need to amend 45 C.F.R. 46, Subpart A for these best practices to have the force of law

- On the issue of ownership – NCI's Best Practices:
  - Use the term "principles of responsible custodianship" instead
  - But acknowledge the potential need to return biospecimens to owners due to cultural practices
    - Question – does this open the "post donative door" to control and ownership?

Past the “informed consent donative door”

- Decision to withdraw participation
- Special accommodations to return biospecimens to donors based on cultural practices
- Or – a different fact pattern – to help the donor’s own health or that of a family member?

Question

- Could there be a limited property right to biospecimens for a patient's own therapeutic benefit?
  - Would involve disentangling the bundle of property rights to address certain types of situations

Is the answer in *Moore?*

- "...it may be that some limited right to control the use of excised cells does survive the operation of this statute."
- "...no need to read the statute to permit scientific use contrary to a patient's expressed wish."

Going Forward

- There is clearly an interrelationship between the interests of the courts, federal agencies, researchers, and patients
- Best practices are extremely important, and may serve as a policy framework for the courts to use in deciding biospecimen-related cases, but they do not have the force of law
- Current federal regulations do not address the complexities of biospecimen research and cannot really be “tweaked” to do so
- Some states are attempting to more fully address these issues