

Custodianship and Ownership Issues in Biospecimen Research Symposium-Workshop

Patient Perspectives on requests for transfer of donated tissue for clinical use – *particularly for use in translational research*

Dear members of the committee:

In the workshop of Oct 4-5 we may not have fully considered that requests for transfer of tissue for clinical use could many times be in harmony with the ultimate objective of achieving “*personalized medicine*,” and the oft-stated principle of “*partnering with patients*” – particularly when used to determine eligibility for clinical trials:

“The trick with molecular targeting is that you have to be able to match the drug to the patient. And until you understand how the drugs work, why they work, and for whom they work, your results might not be as remarkable as you would like for them to be. Once we understand how to match the drug to the patient, I think we will see many, many examples like imatinib [Gleevec].”
~ Dr. Brian Druker, Howard Hughes Medical Institute

And we need to consider that in cases of medical necessity, the transfer of tissue for this purpose, while rare, could be the most ethical use. Moreover, a secondary benefit of allowing for transfer of biospecimens in rare cases of clinical necessity is that it will help to avoid wasteful litigation.

To address concerns about the burden this policy might create on the biorepository system, we propose that from the very beginning a small portion of the disease tissue be snap-frozen and *maintained within the biorepository* and set aside for possible clinical use. This simple step should mitigate concerns about compromising ongoing studies, or having to recall tissue already in use by researchers.

Consent for this provision should be made part of the original informed consent document; obtaining consent for this provision should not be the responsibility of the pathology department or surgical providers. Amended Oct 23, 2007

So we urge the committee to adopt policy and procedures that support transfer of tissue set aside for clinical use (or related analysis information) for the following purposes:

- **To support urgently needed translational research.**

“The number one roadblock to our progress, as defined at the think tank Dialogues on Cancer (2002), is the lack of availability of high quality, highly characterized human specimens for translational research.”

- **To ensure that at least some biorepository-based research is driven by the medical needs of the participants.**

(Instead of rights to biospecimens based solely on IRB and PI interactions, which has an ongoing potential to be influenced by biases and conflicts of interest)

- **To provide a solution for an apparent crisis in clinical research** by making standardized snap-frozen biospecimen available to interventional studies for the purpose of identifying **biomarkers** for drug efficacy and toxicities.

*"... the development path is becoming increasingly challenging, inefficient, and costly." "the two most important areas for improving medical product development are biomarker development and streamlining clinical trials." ~
FDA white paper: The Critical Path.*

- **To avoid an unnecessary competition for participants** between biorepositories and clinical trial investigators and sponsors.
- **To increase incentives for patient participation** in biorepository-based research, and to gain needed support from patient advocacy groups.
- **To foster patient and public trust.**
- **To help meet the urgent clinical needs of the participants** in uncommon cases of medical necessity.

As you know, it's anticipated that standardized biospecimen resources will accelerate discovery of new drug targets and enable more efficient clinical research through discovery and validation of biomarkers. **These pressing needs cannot be met without a supporting infrastructure.** Therefore, a biorepository policy that provides a means to transfer biospecimen for these purposes is urgently needed:

Thank you so much for your attention to patient and caregiver comments on this issue.

Sincerely

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Participant: Biospecimen Access and Ethical, Legal, and Policy Issues Workshop (ELP)
Participant: Custodianship and Ownership Issues in Biospecimen Research Symposium-Workshop

Related Report:

Biobanking of fresh frozen tissue: RNA is stable in nonfixed surgical specimens
<http://www.nature.com/labinvest/journal/v86/n2/pdf/3700372a.pdf>

Our data indicate that nonfixed tissue specimens may be transported on ice for hours without any major influence on RNA quality and expression of the selected genes. However, further studies are warranted to clarify the impact of transport logistics on global gene expression.