



Biospecimens: The Bridge to Personalized Medicine

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The potential of genomics-based research and associated promise of personalized medicine for the first time in history allows us to envision a future where cancer is detected and interventions developed on the basis of specific molecular changes. It is clear that we are living on the cusp of unprecedented change in cancer medicine.

The shift from the traditional biomedical world, in which we slowly and painstakingly seek to understand the origins of disease -- and use trial and error methods to treat patients -- is giving way to a new paradigm. In future years, specific molecular-based technologies will allow us to predict disease predisposition, intervene early or prevent it, and monitor the effectiveness and safety of targeted treatments in real time. Such precision for each patient will comprise this coming era of Personalized Medicine.

However, fully realizing the promise of this new era of medicine will not be easy; especially when it comes to what is perhaps the most critical enabler of genomics-based research -- human biospecimens.

The use of biospecimens in medicine for diagnostic purposes is decades old, and research that is dependent

on the availability of biospecimens (human tissues) is not a new idea. As a result, there are at least 300 million patient samples of various kinds estimated to be stored in U.S. biobanks. (<http://biospecimens.cancer.gov/nbn/rand.asp>)

Unfortunately, most of these samples were collected long before genomic-based research was envisioned, and hence before the special technical requirements for the use of these precious resources could have been known.

Today's challenges in the overall field of human biobanks and biospecimens relate directly to issues surrounding the standardization, collection, archiving, and dissemination of samples; the diligent ethics processes needed to ensure a chain of trust for the patient donor, including the informatics tools needed to de-identify the names of patient donors to protect privacy and confidentiality; and the infrastructure and systems required to enable sharing of precious biospecimens across the research community to accelerate research.

There are many stakeholders with a strong interest in optimizing the nation's biospecimen resources to enable biomedical research:

researchers, clinicians, patients, and healthcare providers

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are all committed to biospecimen-based studies and their positive impact on improving patient care.

To facilitate the evolution of this field, the National Cancer Institute has reached out to collaborate with all these key constituencies over the past five years.

Our role has been three-fold:

- **Convening the Community:** NCI has conducted a number of studies and sponsored conferences on key issues in biospecimen-based research and biorepository management, focused primarily on reaching consensus in the basic, translational and clinical research communities around standards and best practices. In November 2005, NCI sponsored a symposium on International Harmonization of Biorepository Practices, attended by more than 80 biorepository experts from 15 countries in North America, Europe, and Asia to share information on a range of scientific, technical, ethical, legal, and policy issues affecting biospecimens and biorepositories.
- **Harmonizing the Protocols:** NCI has developed First-Generation Guidelines for NCI-Supported Biorepositories, with recommended best practices for research biorepositories; Quality Assurance and Quality Control programs; and implementation of informatics systems. The public was invited to comment on these guidelines earlier this year, and in coming months, a final document will be disseminated to all NCI-supported biorepositories and organizations with an interest in the area.

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- **Accelerating Biospecimen Science:** NCI is also shaping a new generation of evidence-based standards for the collection of biospecimens, to determine which factors have an impact on the biological integrity of samples and thereby affect biomolecules and derivative experimental research outcomes. In March 2006, NCI organized a Biospecimen Research Symposium for government, academic, and commercial research organizations to identify priorities within this newly emerging field of biospecimen science.

As we seek to unlock the mysteries of cancer and other diseases, biospecimens represent the bridge between two key resources: the vast amounts of emerging molecular data and the wealth of medical data that exists in patient histories and clinical outcomes. Biospecimen-based research enables us to explore and identify the molecular “signatures” that are characteristic of certain disease sub-types, and provides a pathway to use those signatures as diagnostic tools and as targets for new drug discovery. They also provide the means for initial testing of new drugs. For patients, they often represent a tangible contribution directly to the research process, and an opportunity to achieve improved future outcomes for family members with similar disease risks.

It is vital that as a community, we harmonize our processes and procedures for biobanking in the 21st century. At stake is the pace -- and the ultimate success -- of our shift towards truly personalized medicine, and the improved diagnostics and therapeutics that will help us to eliminate death and



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suffering from cancer and other devastating diseases in the coming years. The National Cancer Institute invites you to participate in our activities and to follow our progress at <http://biospecimens.cancer.gov>

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BioBankCentral

BioBank Central, a service of FasterCures, educates patients, doctors, researchers, and the public about the critical role that biorepositories play in enabling modern biomedical research.

For more information, visit www.biobankcentral.org.

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