

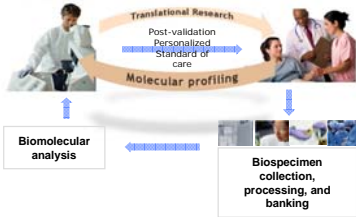
Abstract: Biospecimen Science and the OBRR

High quality biospecimens, annotated with privacy-protected clinical data, are a critical resource to support genomic- and proteomic-based interventions in cancer research. There is considerable heterogeneity in the way that human specimens (tissues and biofluids) are collected, processed, stored, and disseminated, as well as in the management of related ethical, legal and policy issues. There is also limited scientific evidence available relating to how this diversity of specimen handling affects the quality and reproducibility of data from cancer research. It is inevitable that development of new clinical tools will encounter these issues when using biospecimens for the identification of biomarkers and validation of technology. Recently, NCI established the Office of Biorepositories and Biospecimen Research (OBRR) to coordinate biospecimen-policies and practices for NCI-supported biorepository resources and related research. A division of the OBRR, the Biospecimen Research Network (BRN), was formed to perform analytical studies to inform the development of appropriate data-driven, evidence-based practices and protocols for specific specimen types and molecular analysis platforms. The challenge in obtaining high-quality specimens is multifactorial, and the approach for addressing the problem brings together surgeons, pathologists, clinical scientists, research scientists, bioinformaticians, and patient advocates. This poster discusses the different resources available from the NCI and presents the need for additional technologies in the biospecimen sciences.

Biospecimens are Key to the Future of Molecular Medicine

- Understand disease mechanisms using advanced technologies
- Identify and validate new targets for detection, diagnosis, treatment, and prevention
- Develop a molecular-based taxonomy of cancer
- Develop screening tests for biomarkers associated with diseases and drug responses
- Group patients based on biomarkers to determine appropriate treatment

Limited availability of high-quality biospecimens is an important barrier to research progress



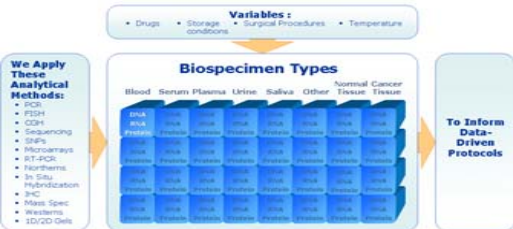
Why is biospecimen quality heterogeneous?

- Variations in **informed consent practices** for donating tissues
- **Methods and practices** for tissue collection, preservation, and information management differ from site to site and among surgical, pathological, and research scientist teams

What is a Biospecimen Resource?

NCI defines 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.

Different morphological and biomolecule analysis techniques may require different methods of tissue preservation



The Biospecimen Research Network: A Transdisciplinary Approach to the Problem

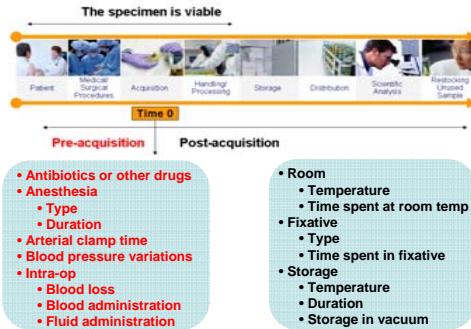
Teamwork across different clinical and research disciplines

- Patients and patient advocates
- Surgeons
- Pathologists
- Nurses and Clinical Scientists
- Biorepository personnel
- Research Scientists
- Bioinformaticians
- Intramural, extramural, military, and industrial partners

The BRN: A network of partners performing research on how biospecimen practices affect research outcomes

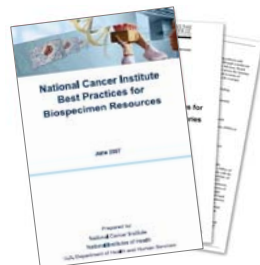
- Plan and execute prospective analytical studies
- Determine how the results of DNA, RNA and protein analysis are affected by defined pre-acquisition and post-acquisition specimen variables

Pre-analytical variables can affect the molecular integrity of biospecimens and profoundly influence experimental results



NCI Best Practices for Biospecimen Resources

Objective: Unify policies and procedures for NCI-supported biospecimen resources



Supporting Innovative Technologies

Innovative Molecular Analysis Technologies Program

<http://imat.cancer.gov>

Rationale

Ensuring that resulting technologies are robust and appropriate for intended applications in basic, preclinical, and clinical settings

By encouraging highly innovative, technology-centric research projects:

- Address the complexity of cancer
- Are designed to interrogate, illuminate, analyze this complexity
- Emphasis on *high-risk, high-impact, early stage* technology
- Emphasis on technology development vs. hypothesis-driven research
- Milestone-based, with performance milestones that *quantitatively* address measures such as specificity, sensitivity, speed, and similar performance parameters that can be used to address whether technology represents an improvement over state-of-the-art and when such technology can move on to the next phase in development
- Staged process requiring quantitative evidence of progress or feasibility before advancement to the next stage
- Small-business funding opportunities:
 - approximately 1/4 of applications
 - approximately 1/3 of awards
- Solicited and funded technologies are multidisciplinary

Cancer Technology and Biospecimen Science

Development of novel technologies require quality biospecimens

- **Discovery, Identification, and Qualification** of valid biomarker targets in tissue, serum, blood, etc.
- **Evaluation, Optimization, and Validation** of technology with clinically appropriate samples

Biospecimen science needs novel technologies

This is a conceptual list of technologies urgently needed in the biospecimen sciences for use in operating suites, pathology labs, biorepositories, and laboratory benches:

Portable and rapid sensors (Lab on a chip)

- Quality assurance that biospecimen hasn't significantly degraded between patient acquisition and the benchtop
- Quantitative tissue analysis (ex. extent of necrosis, etc.)
- Quantitative measures of blood and serum quality
- Methods to measure DNA/RNA integrity
- Many other opportunities....

Portable tracking devices

- Technologies that can track samples with clinically relevant data from the patient to the researcher and are compatible for use in varying environments from an operating room to a laboratory (ex. RFID, portable PDAs)
- Many other opportunities...

Any other ideas?

For more information, please visit:

<http://biospecimens.cancer.gov>



IMAT funding mechanisms

