

Biorepository and Biospecimen Science: A New Focus for *CEBP*

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Biorepository Science

In January 2006, *Cancer Epidemiology, Biomarkers & Prevention (CEBP)* introduced the new subject area of Biorepository and Biospecimen Science. In creating this new category, the journal is recognizing what many investigators, including molecular epidemiologists, have known for years: that the proper collection, processing, storage, and tracking of biospecimens are critical components of biomarker-related studies and collectively merit designation as a science. Epidemiologists, in particular, also recognize the importance of the well-controlled collection of data associated with biospecimens, as it is the combination of proper collection and handling of specimens, along with the accurate collection of study appropriate data about the study participant and specimen quality, that gives biospecimens their long-term value. Additionally, for the biochemical and molecular assays that are such integral parts of epidemiologic studies, the quality of specimens can have profound effects on the results—that is, the laboratory equivalent of garbage in-garbage out of the computer science.

It is well known among investigators who routinely collect and process specimens that, for example, collection and processing times, as well as storage and shipping conditions, can all affect the quality of assays and ultimately the quality of a study. Unfortunately, the results of methods studies that would clarify such issues are not often widely disseminated or published. As a result, much of the knowledge about specific factors that affect biospecimen quality is anecdotal and unreliable. With this new category of Biorepository and Biospecimen Science, *CEBP* encourages investigators to share their experiences, undertake and publish relevant methodologic research, and ultimately raise the bar for the quality of biospecimen research.

The AACR has recognized the importance of biospecimen science for several years. The 1998 Annual Meeting included a methods workshop, "Establishment, Maintenance, and Quality Control of Biorepositories," which highlighted the importance of proper handling and storage of specimens for epidemiology studies. The 2006 meeting in Washington, DC included a methods workshop, "Sample Collection, Processing, and Storage for Large Scale Studies: Biorepositories to Support Cancer Research." Presentations covered establishing data banks and biorepositories; specimen collection, processing, and storage; DNA extraction; and bioinformatics for biorepositories. Those presentations are summarized in this issue. And, of course, since the establishment of the AACR

Molecular Epidemiology Group, many of the Annual Meeting sessions and the special conferences that are Molecular Epidemiology Group sponsored have included presentations on biospecimen science.

During the past 5 years, interest in biorepositories and biospecimen science has grown tremendously and fueled several important national and international initiatives. From the individual patient's perspective, biospecimen research has received a higher profile, as patients have recognized the importance of specimen banking in advancing research agendas and cures for their own diseases. Such recognition has led to exponential growth in the banking of specimens for research purposes. A book published by RAND in 1999 (1) surveyed clinics, laboratories, and commercial and government biorepositories in the United States and concluded that >300 million biospecimens were being stored for research and patient care. Biospecimen collections were estimated to be growing at a rate of >20 million specimens each year. The importance of biorepositories has also gained a higher profile due to four "summits" hosted by IBM during 2004 and 2005 (http://www-03.ibm.com/industries/healthcare/doc/content/resource/insight/1490547105.html?g_type=pspot). The most recent IBM meeting, held in Washington, DC in November 2005, focused on "international harmonization for cancer biobanks."

Biorepositories are established for a variety of reasons and, when operated properly, adhere to a complex set of operating procedures as well as strict ethical and legal standards. A second RAND publication in 2003 (2), "Case Studies of Existing Human Tissue Repositories," outlined best practices in terms of biorepository operations as well as legal and ethical standards. In 1999, the International Society for Biological and Environmental Repositories was established, and its biorepository best practices (3) have helped to focus attention on the many important aspects of proper biospecimen handling as well as the legal and ethical standards and regulations that govern specimen collection.

Over the past 4 years, the National Cancer Institute (NCI) has helped raise awareness of these issues and has begun to address them through its efforts to explore the feasibility of establishing a National Biospecimen Network (4). During 2004, NCI conducted a survey of its biorepository programs that revealed substantial heterogeneity in biorepository management practices across the Institute. The survey results were reported to the National Cancer Advisory Board in 2004 and resulted in further initiatives at NCI, including two workshops during 2005 that focused on the development of specific recommendations on policy and operational issues. These workshops brought together diverse representatives from the cancer research community with the expertise to help formulate recommendations to unify, integrate, and improve the transparency of NCI-supported biorepository activities.

In late 2005, NCI established a new Office of Biorepositories and Biospecimen Research (<http://biospecimens.cancer.gov/>).

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The Office of Biorepositories and Biospecimen Research has published new, voluntary guidelines for NCI-supported biorepositories. These initial guidelines, which can be viewed on the Office of Biorepositories and Biospecimen Research Web site, are based on well-established practices within the biorepository community. More comprehensive guidelines will follow based on a new NCI biospecimen research program that will begin to address unresolved biospecimen issues, publish results, and give proper recognition to the methodology studies that have traditionally been considered a low-profile, low-importance activity.

Biospecimens are collected under a variety of protocols for many reasons, including basic methods research and assay development, clinical trials, and epidemiology studies. As discovered in the NCI survey, however, given the number and scope of studies involving biospecimens, approaches to procedural, legal, and ethical issues are inconsistent. Larger commercial biorepositories are usually operated under strict quality assurance programs. Smaller academic and government biorepositories, with one or a few freezers for tissue storage, may not realize the need to adhere to the highest biorepository standards or cannot afford to adhere to such standards. Often, the standard procedures used in biorepositories are not so "standard," institutional review board

reviews and consent forms are inconsistent, inventory systems and other bioinformatics are rudimentary, and regulations to guard patient privacy are not always well understood or followed. Generally, there is a lack of evidence-based standards for biorepositories.

With so many unresolved technical, ethical, legal, and other issues associated with biorepository and biospecimen science, *CEBP* inaugurates this new subject area with the hope that its reputation for publishing papers of the highest quality will increase the profile of this field and will stimulate and articulate research papers that will serve to accelerate progress in epidemiology, prevention, early detection, and other areas that rely on biorepositories and biospecimens.

References

1. Eiseman E, Haga SB, editors. Handbook of human tissue sources: a national resource of human tissue samples. Santa Monica (CA): RAND Corp.; 1999.
2. Eiseman E, Bloom G, Brower J, et al., editors. Case studies of existing human tissue repositories: "best practices" for a biospecimen resource for the genomic and proteomic era. Santa Monica (CA): RAND Corp.; 2003.
3. ISBER (International Society for Biological and Environmental Repositories). Best practices for repositories I: collection, storage, and retrieval of human biological materials for research. *Cell Preserv Technol* 2005;3:5-48.
4. Friede A, Grossman R, Hunt R, et al., editors. National Biospecimen Network Blueprint. Durham (NC): Constella Group, Inc.; 2003.