Biorepository book helps programs follow guidelines

Bridget Kuehn

December 2014—Securing financial support and setting up a quality management program are two of the biggest challenges to creating a successful biospecimen repository, says Nilsa C. Ramirez, MD, director of the Biopathology Center of the Research Institute at Nationwide Children's Hospital in Columbus, Ohio.

As chair of the CAP Biorepository Accreditation Program Committee, Dr. Ramirez has seen firsthand what can trip up biospecimen repository programs that seek to earn CAP accreditation. Finding staff with the right expertise and accounting for research-specific requirements are other common challenges.

Now, a new CAP Press book, *Developing and Organizing an Institutional Biospecimen Repository*, can help program directors and pathologists establish a new biorepository or improve an existing one. The two editors and 15 contributors provide detailed information about how to get started, personnel, infrastructure, biospecimen flow, QC, informatics, informed consent, cost assessment, and more.

"It will help them get a very organized approach to how to set up a biorepository," says Dr. Ramirez, who co-wrote the chapter on management and key personnel.

Dr. Hansel

Donna E. Hansel, MD, PhD, co-editor of the book, says careful planning is required to develop the internal and external partnerships that will support the biorepository long term. Dr. Hansel, division chief of anatomic pathology and professor of pathology at the University of California, San Diego, says although some biorepositories can be self-supporting financially, others may need to secure funding or other institutional support to meet end-user needs. Those who seek to build a repository should thus obtain buy-in from hospital leaders and other departments that would benefit from the repositories.

"It's important that we do it right and do it collaboratively," Dr. Hansel says. "It's not something that is as simple as it used to be. People need to be aware of all the aspects of running a repository so they can do it right from the beginning."

Fully integrating a biospecimen repository into the institution also is critical to ensuring the samples are of high quality. Scott D. Jewell, PhD, co-editor of the book and director of the program for biospecimen science at the Van Andel Research Institute in Grand Rapids, Mich., says the key to sample quality is shortening the time between sample collection and preservation. Doing so requires cooperation from surgeons and other clinical staff "and a clear understanding of your processes."

"It really needs to be driven by the biobank," Dr. Jewell says.

Dr. Jewell

Dr. Jewell co-wrote (with David Chesla of Universal Biorepository, Spectrum Health, and Daniel Rohrer of Van Andel) the book's chapter on establishing a flow for biospecimens. They cover, among other things, standardization of collection using biospecimen kits (see book excerpt, page 48), participant identification and informed consent, tissue collection policies, storage, and distribution.

"Better biorepositories better serve research and, hopefully, better serve clinical care," Dr. Jewell says.

Having consistent protocols and carefully documenting biospecimen handling are essential to providing researchers with usable samples, says Sarah M. Dry, MD, who co-wrote (with Clara Magyar, PhD, of UCLA) the book's chapter on specimen quality control. Researchers need to know how a sample was handled to know if it will be appropriate for their study.

Dr. Dry

Dr. Dry, co-director of the Translational Pathology Core Laboratory at UCLA, says if a sample had thawed or thawed partially during a freezer failure, for example, it could affect the levels of specific analytes in serum or plasma, particularly if the biosample experienced more than one freeze-thaw cycle. But this same sample may be acceptable for another project. The key is making sure the documentation is available to allow researchers to make the best choices about whether the samples are suitable for their studies, she explains.

"Pathologists must understand that the 'best' collection, processing, preservation, and storage method for a sample depends on its intended use," she says.

Formalin fixation with paraffin embedding (FFPE) and sectioning would be recommended for "best" tumor tissue histology. But for RNA studies, Dr. Dry says, FFPE tissue may be "suboptimal or unacceptable depending on the specific use, while rapidly snap frozen tissue is optimal." In setting up a biorepository, she says, "pathologists must understand the intended end uses by researchers and put appropriate protocols in place that span the full lifespan of the biosample." If the intended use is unknown, Dr. Dry recommends that pathologists set up protocols suited to the most likely uses of the specimens.

Pathologists must have "well-written, internally consistent protocols, good documentation, well-trained staff, and a strong quality management program" to maintain high-quality samples in their biobanks, she says.

Consistency across institutions is also important. While the National Cancer Institute was working to develop The Cancer Genome Atlas, Carolyn Compton, MD, PhD, former director of the NCI Office of Biorepositories and Biospecimen Research, contacted biorepositories across the country to find suitable tissues for the project. But she discovered that the processes used to collect the samples and the data associated with them were not standardized across institutions. There were important variations in the time between tissue collection and fixation. Quality control checks for RNA degradation in samples also varied. So, too, did the specimen-associated consents

for research, which Dr. Compton tells CAP TODAY precluded the use of many samples for The Cancer Genome Atlas.

The right kind of specimen sets were another problem. “For TCGA, we needed a sample of normal tissue as well as the cancer from the patient,” she says. “Otherwise mutation calling was impossible.” But she says many institutions or biospecimen collections had no stored blood or other normal tissue from the same patient.

Finding biobank staff with the right expertise can be difficult. Dr. Ramirez says those who have been working in hospital laboratories may not be familiar with some of the unique requirements of biorepositories. They may not be familiar, for example, with material use agreements, research regulations, or bioinformatics. The book’s descriptions of the personnel needed for a biorepository and the experience they should have, she says, will help biorepository directors train their staff or even “discover” existing staff with the relevant skills.

The book was designed, Dr. Jewell says, to aid biorepositories in following the guidelines set out by the Office of Biorepositories and Biospecimen Research (NCI Best Practices for Biospecimen Resources, http://biospecimens.cancer.gov/bestpractices) and the International Society for Biological and Environmental Repositories (www.isber.org/?page=BPR).

It will also be useful to those pursuing CAP accreditation through the Biorepository Accreditation Program, launched in 2012. Dr. Jewell, a member of the BAP committee, says the program leverages the CAP’s experience with laboratory accreditation to help biorepositories meet the highest operational standards. Peer reviewers help assess each participating site and make recommendations for improvement. To date, 55 biorepositories have applied to the accreditation program and 29 have been accredited. Dr. Jewell expects that more institutions will seek accreditation for their biorepositories because it gives them an edge when seeking funding and research partners.

Dr. Hansel says the book will be equally useful to small biobanks and large, centralized repositories. She adds, “This is basically a companion guide that can help people navigate the CAP accreditation program.”
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Bridget Kuehn is a writer in Chicago. To purchase a print book (PUB314), go to www.cap.org (“Shop” tab). To purchase an ebook, go to ebooks.cap.org. Or call 800-323-4040 option 1. List price: $90. CAP member price: $72. Ebook price: $63.