Biospecimen Research and Informed Consent: AAHRPP Conference Helps Move the Discussion Forward

When the Department of Health and Human Services (DHHS) releases its much-anticipated notice of proposed rulemaking (NPRM) on protecting research participants, some in the research community will pay particular attention to proposals governing informed consent for biospecimen research.

The decades since the last major revision to the Common Rule have brought significant advances in biomolecular and information technology—and unprecedented opportunities to learn more about genetic variation and its role in combating disease. With those advances have come new questions about how best to approach informed consent for research involving biospecimens, especially those that might be stored indefinitely.

In fact, proposed changes to informed consent for biospecimens—outlined in the July 2011 DHHS advance notice of proposed rulemaking (ANPRM), Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators—generated more comments than any other topic covered by the ANPRM. Among the questions asked:

- Will informed consent be required for all biospecimens?
- Will new regulations apply to previously collected, de-identified samples?
- Will new regulations apply to samples left over from clinical procedures?
- What type of consent will be required for future use of newly obtained specimens?
- Will all specimens, regardless of level of identifiability, be treated as “subjects”?

Suzanne M. Rivera, Ph.D., M.S.W., Vice President for Research at Case Western Reserve University, raised some of these issues during her presentation, “Collaborations: Challenges Associated With Sharing of Biospecimens and Data,” at the AAHRPP conference this spring. The annual event draws professionals from across the global research enterprise to discuss the latest information on AAHRPP accreditation and other research trends.

Dr. Rivera focused on three studies, funded by the National Institutes of Health’s National Human Genome Research Institute, that were prompted by the hypothesis that differences in policies and procedures for informed consent and specimen sharing might inhibit or even prevent research collaborations. A key concern, Dr. Rivera says, is whether “the variability in policies creates obstacles for investigators who want to pool specimens and data to answer important scientific questions.”

Dr. Rivera and colleagues from Case Western Reserve University, the Hastings Center, Nationwide Children’s Hospital, the University of Pennsylvania, and the University of Utah designed and conducted the studies to assess institutional review board (IRB) practices, institutional policies, and researchers’ attitudes on informed consent and sharing of biospecimens. Results will shape recommendations on what to cover during informed consent discussions, how and where biospecimens should be stored, and who should have access to them.
Seeking consensus
The studies found some variability in IRB practices, institutional policies, and investigator opinions but little evidence that these differences have created obstacles. To prevent the lack of consensus from impeding collaboration, the study team very likely will recommend that institutions and IRBs work together to answer serious questions.

For Dr. Rivera, one area of interest is the standard that IRBs use when deciding whether to grant requests to tap banked specimens for new research. Sixty-nine percent of IRB directors participating in the study said their decision would be based on whether the new research is “not inconsistent” with the uses covered by the original consent. Thirty percent would consider whether the new research is “consistent” with the original uses.

“Being ‘consistent’ is a more rigorous standard, whereas ‘not inconsistent’ is a more practical one,” Dr. Rivera explains. If, for example, a research participant originally granted permission for tissue to be used in a study of breast cancer, future “consistent” uses might be restricted to other cancer studies. If the standard for permission is uses that are “not inconsistent,” samples could be used for almost any study on human disease.

“So many consent forms are being written without any thought to potential future uses and to what we value as a society—the rights of the individual or the good of the whole group,” Dr. Rivera says. “What is reasonable informed consent?”

At the heart of the issue is the struggle to strike a balance between the rights of research participants and the potential humanitarian benefits of new knowledge. “To what degree do we privilege respect for persons and autonomy over other important ethical principles, such as beneficence and justice?” Dr. Rivera says.

She and her team of researchers are poised to help answer those questions. In November, they’ll present the results of their studies—and their recommendations—at the Specimen Science: Ethics and Policy Implications conference at the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School. Their goal is to continue the discussion, help create consensus, and promote responsible use of banked biospecimens.