AAHRPP ADVANCE
One Standard Worldwide
SUMMER 2015

Furthering the Discussion on Biospecimen Research and Informed Consent

Advances in biomolecular and information technology offer unprecedented opportunities for discovery. These advances also raise new questions about how best to approach informed consent for research involving biospecimens, especially those that might be stored indefinitely. **LEARN MORE**

Conference Posters Address Today's Research Protection Issues

The 2015 AAHRPP Conference featured a record number of research posters. Here we provide a sample of some of the topics covered, from innovative collaborations and quality improvement to determining whether war refugees are "vulnerable populations." **LEARN MORE**

Metrics Provide Basis for Comparison, Improvement

President and CEO Elyse I. Summers, J.D., shares highlights from AAHRPP's "2014 Metrics on Human Research Protection Program Performance." Available **online**, the report is designed to help you compare your organization's performance with that of your AAHRPP-accredited peers. **LEARN MORE**

2016 Conference: Save These Dates

The 2016 AAHRPP Conference will be held April 19-21 in Long Beach, California. Please reserve these dates and watch for more details in the coming months. **LEARN MORE**

SUMMER 2015

INSIDE

Latest Accreditations

- **Loyola University Chicago, Health Sciences Division,** Maywood, Illinois
- **Peking University,** Beijing, China
- **Taipei Medical University - Shuang Ho Hospital,** New Taipei City, Taiwan
- **Taipei Municipal Wanfang Hospital, Taipei Medical University,** Taipei, Taiwan
- **Texas A & M University,** College Station, Texas
- **University of California, Davis,** Davis, California
- **University of Miami,** Coral Gables, Florida

LEARN MORE

AAHRPP®
Association for the Accreditation of Human Research Protection Programs, Inc.®

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

SUZANNE M. RIVERA, PH.D., M.S.W.

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

CONTINUED PAGE 3

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.

Conference Posters Explore Today's Research Protection Challenges

The 2015 AAHRPP Conference featured more than 30 posters on topics ranging from innovative collaborations and quality improvement to setting best practices for biorepositories, registries, and databases and determining whether war refugees are "vulnerable populations."

AAHRPP received a record number of submissions this year, and more than 15 percent came from organizations outside the U.S. The posters tackled weighty questions facing the research enterprise.

"This year's posters reflect the increasingly global nature of the research enterprise and AAHRPP's influence," says Sarah Kiskaddon, J.D., M.A., AAHRPP Director of Global Development and Public Affairs. "Presenters addressed complex issues and shared insights and best practices that will help advance ethical research and research protections."

The following sample represents participating organizations and poster topics:

- From American University of Beirut: "Should refugees from countries at civil war be regarded as vulnerable populations?"
- From Biomedical Research Alliance of New York (BRANY): "Managing non-compliance: A systematic approach that improves human subject research protections"
- From Florida Department of Health and University of Florida: "Academy of Research Excellence: An education program to build research collaborations and improve participant protections"
- From Donald Guthrie Foundation: "Using the electronic health record to efficiently prescreen potential research subjects"
- From Ann & Robert H. Lurie Children's Hospital of Chicago and Stanley Manne Children's Research Institute: "Administering investigational drugs and devices outside an approved protocol: Helping investigators and IRB staff/chair navigate federal regulations"
- From Morehouse School of Medicine: "Community engagement in research: A strong and effective relationship between the community, researchers, and IRB"
- From National Taiwan University Hospital and Center of Drug Evaluation: "Innovative IRB collaboration for multicenter clinical trials: Efficiency review with quality oversight"

CONTINUED PAGE 4

- From North Shore-LIJ Health System: "Transformation to an all-videoconference flexible IRB model: One institution's experience"
- From Peking Union Medical College Hospital: "The need for standardization of recruitment advertisements in China"
- From Peking University Health Science Center and the University of Michigan: "International Joint Institute at Peking University and the University of Michigan develops joint protocol review system"
- From Seattle University: "The establishment of institutionally appropriate incentive payment policy limits for human subjects research"
- From Tata Memorial Centre, India: "The role of accreditation in quality improvement of the institutional review board"
- From Department of Pediatrics, University of Connecticut School of Medicine; Division of Pediatric Neurology, Connecticut Children's Medical Center; and Health Fellows Program at Trinity College: "Parental opinion about pediatric biospecimen permission"
- From University of Cincinnati, Cincinnati VA Medical Center, Medical University of South Carolina, and National Institutes of Health/National Institute of Neurological Disorders and Stroke: "Cooperative review process of the NIH StrokeNet Central Institutional Review Board"
- From Yale University, Van Andel Institute, and National Comprehensive Cancer Network: "National Comprehensive Cancer Network's points to consider on the best practices for biorepositories, registries, and databases"

2016 AAHRPP Conference: Save These Dates

SAVE THESE DATES

April 19-21, 2016
Long Beach, CA

The 2016 AAHRPP Conference will be held April 19-21 in Long Beach, California. Please reserve these dates and watch for more details in the coming months.

AAHRPP®
Association for the Accreditation of Human Research Protection Programs, Inc.®

From the President and CEO

Metrics Provide Basis for Comparison, Improvement

ELYSE I. SUMMERS, J.D.

In keeping with AAHRPP's emphasis on continuous quality improvement, every year we collect data from our accredited organizations and share the findings with you in our report "Metrics on Human Research Protection Program Performance."

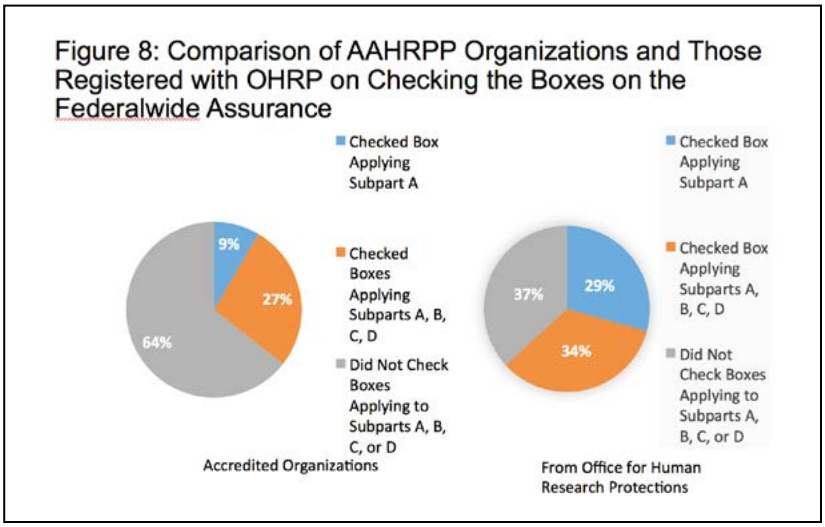
The **2014 metrics**, now available on our website, include fascinating information on five-year trends in areas such as mean IRB review times, number of active protocols reviewed, and internal for-cause audits of researchers and IRB records. To those of us at AAHRPP, one of the most interesting findings is that AAHRPP-accredited organizations are significantly less likely than non-accredited entities to "check the box" on the federalwide assurance—a decision that gives IRBs more flexibility while maintaining research protections.

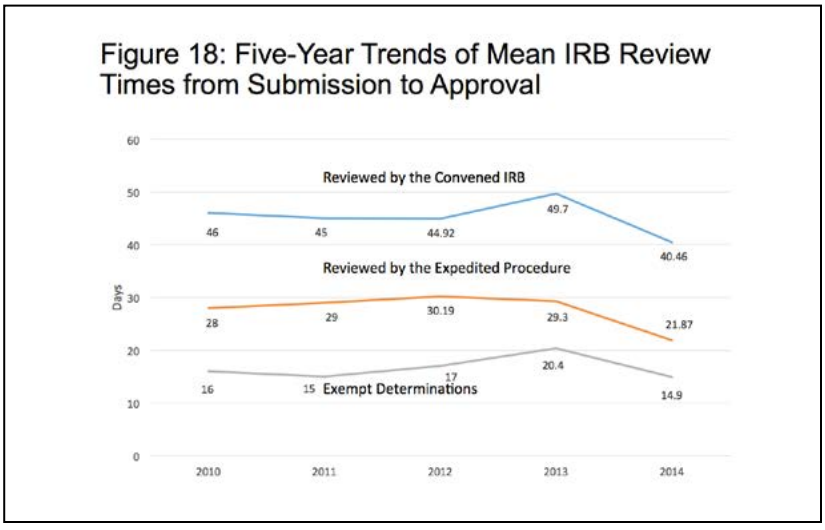
We encourage you to spend some time perusing the metrics report. To whet your appetite, I've provided highlights here:

- **Unchecking the box:** Sixty-four percent of AAHRPP-accredited organizations did not check any of the boxes (subparts A, B, C, or D) within the federalwide assurance (FWA), compared with 37 percent of non-accredited organizations that have an FWA on file with the Office for Human Research Protections (OHRP). Only 9 percent of AAHRPP-accredited organizations checked the box for subpart A, compared with 29 percent of non-accredited organizations.

- **Number of active protocols:** Over the past five years, the mean number of active protocols reviewed by IRBs at AAHRPP-accredited organizations has remained about the same. In 2014, the mean was 1,259, an increase of less than 1 percent from the mean of 1,190 in 2010.

- **IRB review times:** Researchers are reaping the benefits of more efficient IRBs, which now take less time to make decisions about exemptions and to conduct protocol reviews. Since 2010, the average number of days from submission to approval by the convened IRB has dropped from 46 to 40.46 days, and from 28 to 21.87 days for review by the expedited procedure. Decisions on exempt determinations took an average of 14.9 days in 2014, compared with 16 days in 2010.





- **For-cause audits:** The mean number of internal for-cause audits of researchers has dropped from 7.1 in 2010 to 4.7 in 2014. Internal for-cause audits of IRB records decreased from a mean of 4.4 in 2010 to 1.9 in 2014.

- **Use of technology:** IRBs are taking advantage of today's technology, with 87.1 percent distributing materials electronically. In addition, 61.3 percent use an online IRB application, and 64.5 percent use an online system for IRB reviews. Those are significant increases since 2010, when 62 percent distributed materials electronically, 42 percent had an online IRB application, and 43 percent had an online system for IRB reviews.

The metrics are designed to help you compare your organization's performance with that of your AAHRPP-accredited peers—to identify and applaud areas of strength and to target those in need of improvement. If you have questions or would like more information, please don't hesitate to contact Sarah Kiskaddon, M.A., J.D., Director, Global Development and Public Affairs, at **skiskaddon@aahrpp.org** or (202) 783-1112.

In other news, I'm thrilled to announce that **Michelle Feige, M.S.W., L.C.S.W.-C**, has joined AAHRPP as Executive Vice President. She'll play a key role in strategic planning and managing all aspects of AAHRPP's operations. I had the privilege of working with Michelle at OHRP, and we look forward to accomplishing much together at AAHRPP. Her combination of experience, skill, and energy will be an enormous asset to our organization.

Finally, I ask you to save the dates of April 19-21 for the 2016 AAHRPP Conference, which will be held in Long Beach, California. Since it falls one month before the 15th anniversary of AAHRPP's incorporation, the conference will provide an ideal opportunity to celebrate our achievements—and to recognize those of you who've contributed to our success.

Best regards,

Elyse I. Summers, J.D.
AAHRPP President and CEO