AAHRPP ADVANCE
One Standard Worldwide
SPRING 2019

AAHRPP Taps Experts to Help Organizations with Revised Common Rule

Attendees of the upcoming AAHRPP Annual Conference will hear from some of the most respected leaders from across the research community. Hot topics include harmonization in the era of the new rule, informed consent, genetic research, and more. **LEARN MORE**

New This Year: Special "CAN" Pre-Conference Meeting for Accredited Organizations

For the first time, the AAHRPP conference will feature two pre-conference meetings. Pre-Conference A provides an overview for organizations seeking accreditation or reaccreditation. Pre-Conference B—for accredited organizations only—will be the inaugural meeting of our Collaborative AAHRPP Network (CAN). **LEARN MORE**

From the President and CEO

AAHRPP President and CEO Elyse I. Summers, JD, showcases the AAHRPP Annual Conference—and why it remains a must for those concerned with high-quality, ethical research and strong protections for participants. **LEARN MORE**

Register Today

Join us May 21-23 for the AAHRPP Annual Conference: "Big Ideas and Ethics in the Big Easy." **REGISTER ONLINE**

We've Moved!

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SPRING 2019

INSIDE

NEW AAHRPP TEAM MEMBERS

Please join us in welcoming the following to the AAHRPP team: **Mary Fields**, CIP, Quality Assurance Manager; **Dominique Hunter**, Executive Assistant; **Danielle Randolph**, Administrative Assistant; and **Jemelle Williams**, Operations Coordinator.

LATEST ACCREDITATIONS

- **Harvard Pilgrim Health Care Institute, LLC, of Harvard Pilgrim Health Care, Inc.**, Boston, Massachusetts
- **Kaohsiung Medical University Chung-Ho Memorial Hospital**, Kaohsiung, Taiwan
- **Memorial Health Services**, Fountain Valley, California
- **National Cheng Kung University Hospital**, Tainan City, Taiwan
- **Prime Review Board, LLC**, Rockville, Maryland
- **University of Maryland**, College Park, Maryland
- **University of Nevada**, Las Vegas, Nevada

AAHRPP Taps Experts for Conference, Webinar

Hot topics include harmonization, informed consent, genetic research

AAHRPP has assembled some of the most respected leaders from across the research community to help accredited and not-yet-accredited organizations understand and comply with requirements of the updated Common Rule.

In February, the AAHRPP webinar on "Exploring Understanding of 'Understanding': The Meaning and Implications of Informed Consent Comprehension" drew more than 250 attendees. Hundreds more are expected to turn out in New Orleans May 21-23 for the 2019 AAHRPP Conference: "Big Ideas and Ethics in The Big Easy."

"Our conference brings together people from all sectors of the research enterprise," AAHRPP President and CEO Elyse I. Summers, JD, says. "There's no better opportunity to hear the most-informed opinions on today's research challenges—and to collaborate on solutions."

For example, the opening plenary session, "Harmonization in the Era of the New Rule," features Jonathan M. Green, MD, MBA, Director, Office of Human Subjects Research Protections for the National Institutes of Health (NIH); Heather H. Pierce, JD, MPH, Senior Director for Science Policy and Regulatory Counsel at the Association of American Medical Colleges; and Ivor Pritchard, PhD, Senior Advisor to the Director in the Office for Human Research Protections in the U.S. Department of Health and Human Services.

Other sessions address topics including big data, the European Union's General Data Protection Regulation, right-to-try vs. expanded access, international research under the new rule, and limited IRB review. Issues related to single IRB review, including best practices and staffing and budgeting, are also on the agenda.

Seeking Clarity on Informed Consent

Since some of the most significant changes to the Common Rule involve informed consent, AAHRPP's first educational webinar of 2019 focused on that topic. The 2019 annual conference includes multiple sessions on consent-related concerns.

The new rule adds some requirements and terminology that raise questions. For example:

- What is the definition of a "reasonable person" under the new reasonable person standard?
- What qualifies as "key information"?
- How much comprehension is necessary, especially for complex subjects such as biobanking? And, can donors who don't fully comprehend biobanking still consent to provide specimens?

Laura M. Beskow, PhD, MPH, Professor of Health Policy, and Ann Geddes Stahlman Chair in Medical Ethics at Vanderbilt University School of Medicine, and Carol J. Weil, JD, Program Director, Ethical and Regulatory Affairs at the U.S. National Cancer Institute, tackled the last two questions during the February webinar. Weil will touch on other consent-related issues during the AAHRPP conference closing plenary, a panel discussion on "Is There a Right Not to Know Your Genetic Data?"

Dr. Beskow's webinar presentation challenged attendees to consider the role of comprehension in informed consent, including whether there should be a threshold for understanding—and consequences if that threshold is not met. In other words, if, after reviewing the materials, prospective participants do not demonstrate sufficient understanding, should they still be permitted to enroll in the research?

In a recent study on informed consent for biobanking (forthcoming in the May issue of the *American Journal of Bioethics*), a majority of experts supported setting a threshold for adequate understanding. Because the risk is low and other protections are in place, experts believed the threshold should be low—but many expressed great discomfort at the prospect of not allowing willing individuals to enroll.

Weil discussed the rights of potential participants to be educated about the research and the duty of the research team/biobank to disclose information relevant to making an informed decision. However, she also noted that, in her opinion, the regulatory criteria for informed consent do not include the right to understand key elements of the research.

"Disclosure of information is instantaneous, whereas comprehension evolves over time," Weil said. "There is still value in communicating information via the consent process, even if it is not immediately understood."

During the closing plenary, Weil; Benjamin Berkman, JD, MPH, faculty member in the NIH Department of Bioethics and head of the section on the ethics of genetics and emerging technologies; Barbara E. Bierer, MD, Professor of Medicine at Harvard Medical School and the Brigham and Women's Hospital; and Jill Opalesky, MS, Assistant Professor at the Virginia Institute for Psychiatric and Behavioral Genetics, Virginia Commonwealth University, will discuss the controversial so-called "right not to know" and the implications for IRBs that are reviewing genetic research.

"Anyone who has attended an AAHRPP conference knows that we don't shy away from the difficult issues," Summers says. "Instead, in keeping with our role as a resource, we convene the research community, debate and discuss, and strive for consensus whenever possible."

There's still time to save your place at the 2019 AAHRPP Annual Conference. Online registration continues through April 29.

New This Year: Pre-Conference Offers Something for Everyone

Separate sessions for accredited and not-yet-accredited organizations

The Collaborative AAHRPP Network (CAN) will make its debut next month during a special pre-conference meeting—for accredited organizations only—at the AAHRPP Annual Conference in New Orleans. The AAHRPP conference also will include the usual "Overview of AAHRPP" pre-conference meeting for organizations interested in pursuing accreditation for the first time or applying for reaccreditation.

Both pre-conference meetings are full-day sessions and will be held May 21. The main conference follows on May 22 and 23.

Pre-Conference A: AAHRPP Overview

Whether you're new to accreditation or are preparing for reaccreditation, the "AAHRPP Overview" offers invaluable insights into the accreditation process and AAHRPP standards and procedures.

This pre-conference track also provides opportunities to meet representatives of AAHRPP-accredited organizations and hear, firsthand, how accreditation has helped strengthen their HRPPs and elevate their institutions.

Pre-conference topics include:

- An overview of AAHRPP and its singular role in the research enterprise.
- What to expect during the accreditation process.
- How to conduct the self-assessment.
- What to expect during and after your site visit.
- Review of accreditation standards, including those that may present the biggest challenges for your organization.

All presenters are highly experienced members of the AAHRPP Council on Accreditation, which reviews accreditation applications and reports, and makes the accreditation decisions. All council members have extensive experience as site visitors.

Pre-Conference B: New CAN

The CAN is a pilot program to provide a forum for representatives of accredited organizations to exchange ideas, share best practices, and discuss challenging and emergent HRPP issues.

The goal is to convene the group several times a year, including at least once in person. Since so many representatives routinely attend the AAHRPP conference, a pre-conference meeting seemed the ideal choice.

The inaugural CAN agenda includes discussions on:

- The CAN visions and goals.
- Best practices for implementing key provisions of the revised Common Rule.
- Unanticipated problems with broad consent.
- Setting priorities for refining/updating AAHRPP tip sheets—and creation of a subcommittee to advance this project.

AAHRPP President and CEO Elyse I. Summers, JD, sees enormous potential in providing a formal vehicle for collaboration. "It is our hope that the CAN will facilitate even greater understanding and awareness of issues of importance to all whose role it is to help protect the human participants who make the research enterprise possible," she says.

Register online—and view the complete agenda—for the AAHRPP Annual Conference and for either of the pre-conference meetings.

From the President and CEO

ELYSE I. SUMMERS, JD

Our conference tradition: collaboration, innovation, and leadership

When we gather in New Orleans next month, it will mark the 15th time the research community has come together to support accreditation and its pivotal role in protecting the volunteers who make research—and the resulting advances—possible.

Much has changed in the years since AAHRPP's first conference in March 2005. Back then, fewer than 25,000 studies were registered on clinicaltrials.gov. As of April 1 of this year, there were more than 300,000 registered worldwide, reflecting the global nature of today's research enterprise.

AAHRPP has "gone global" as well. Across the U.S. and in Belgium, Brazil, Canada, China, India, Mexico, Republic of Korea, Saudi Arabia, Singapore, South Africa, Taiwan, and Thailand, organizations rely on AAHRPP standards to guide research policies and practices. That speaks volumes about the flexibility and universal value of AAHRPP accreditation.

How did we get here? Those of you who know our history are aware of the pivotal role of our Founding Members and early adopters of accreditation. They have been followed, year after year, by organizations that have committed to maintaining and furthering AAHRPP's high standards—within and beyond their own HRPPs. That commitment will once again be on display at this year's conference, where leaders in science, medicine, ethics, law, and public policy will join AAHRPP in presenting "Big Ideas and Ethics in the Big Easy."

Because the AAHRPP conference typically addresses the most pressing research and accreditation concerns, expect to learn a great deal about the revised Common Rule, including creative and innovative ways to implement it within your organization. We also will take on complex issues such as big data, responding to scrutiny (the CLOVER study), and dealing with disaster (Ochsner Medical Center and Hurricane Katrina).

If your organization is not yet accredited, count on lots of support and encouragement as you prepare to move ahead with the accreditation process. And, for the first time, accredited organizations are invited to a special pre-conference meeting to help launch the Collaborative AAHRPP Network (CAN). This is a wonderful opportunity to share ideas and best practices with your accredited colleagues and to help shape the future of research protections.

It's also just one of many reasons I hope to see you in New Orleans May 21-23. I am confident that—both during and after the conference—together we will continue to advance accreditation, enhance the quality of research, and strengthen protections for research participants.

As they say in New Orleans, "Laissez les bon temps rouler! (Let the good times roll!)"

Elyse I. Summers, JD
AAHRPP President and CEO

Save the Date

Hyatt Regency Baltimore, Maryland

2020 AAHRPP Annual Conference

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

SAVE THE DATE

May 19-21, 2020

More details to follow.
Meanwhile, mark your calendars for one of the research community's must-attend annual events.