AAHRPP ADVANCE
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WINTER 2020

What's Next for HRPPs? Experts Offer Insights

Four AAHRPP site visitors who are experts in research participant protections share their views on the biggest challenges facing today's HRPPs. All four—John Andrew Bertolatus, MD; Ann Johnson, PhD, MPH, CIP; Julie Ozier, MHL, CHRC, CIP; and Linda (Petree) Mayo, CIP—view the new Common Rule requirement for single IRB review for multisite research as the most pressing challenge. Their list also includes concerns about compliance and protecting privacy in a digital world. **LEARN MORE**

Advocating for Patients and for AAHRPP

A cancer survivor and former clinical trial participant, Chris States holds a singular place on the AAHRPP Board of Directors. He is the patient advocate on a board where most members represent organizations that conduct or oversee research involving people who've been in his shoes. **LEARN MORE**

Join Us May 19-21 for 'Challenge and Change in Charm City'

True to tradition, the 2020 Annual AAHRPP Conference promises to be a must-attend event, with thought-provoking presentations, a private movie screening, and plenty of networking opportunities. **LEARN MORE**

From the President and CEO

AAHRPP President and CEO Elyse I. Summers, JD, shares some of AAHRPP's successes as a partner, educator, convener, and resource in 2019. She also discusses what to expect in the coming year. **LEARN MORE**

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WINTER 2020

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LATEST NEWS

AAHRPP model featured in SOCRA journal: Elyse I. Summers, JD, President and CEO, and Michelle Feige, MSW, LCSW-C, Executive Vice-President, co-authored "Establishing a High-Quality Human Research Protection Program: The AAHRPP Model." The article is featured in the November 2019 issue of SOCRA Source, published by the Society of Clinical Research Associates.

What's Next for HRPPs? Experts Offer Insights

AAHRPP recently reached out to four AAHRPP site visitors who are experts in research protections, seeking their input on the biggest challenges facing today's HRPPs. All four—John Andrew Bertolatus, MD; Ann Johnson, PhD, MPH, CIP; Julie Ozier, MHL, CHRC, CIP; and Linda (Petree) Mayo, CIP—view the new Common Rule requirement for single IRB review for multisite research as the most pressing challenge. Their list also includes concerns about compliance and protecting privacy in a digital world.

The single IRB mandate

The Common Rule requirement for single IRB review took effect January 20, two years after the change was announced. Organizations have used that time to prepare but remain concerned both about the impact on IRBs and the ripple effect throughout HRPPs.

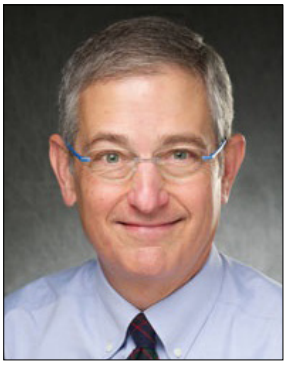
JULIE OZIER, MHL, CHRC, CIP

"Once the IRB review piece is extracted from the HRPP, smooth operations are disrupted," says Ms. Ozier, HRPP Director for Vanderbilt University and Vanderbilt University Medical Center, and a member of the AAHRPP Council on Accreditation. "That has left many scrambling to figure out how to remain aware of the activities at their organization when an outside entity is conducting the in-depth protocol review. This will require some re-engineering of the workflow and processes each HRPP has in place."

Dr. Johnson, Director of the Institutional Review Board at The University of Utah, also expects changes at the HRPP level. "HRPPs are having to clearly delineate the difference between the IRB role and the HRPP role," she says. In the past, "many institutions just lumped these together. But in order to streamline the process for using a single IRB, this refinement needs to happen."

ANN JOHNSON, PhD, MPH, CIP

Dr. Bertolatus, Associate Professor Emeritus of Internal Medicine and Primary IRB Chair for the biomedical IRB at The University of Iowa, anticipates oversight challenges for both the IRB of record and the organizations that cede responsibility for review.



JOHN ANDREW BERTOLATUS, MD

"The new mandate fails to take into account the fact that IRB review of biomedical studies of greater than minimal risk usually involves ancillary committees—for pharmacy review, conflict of interest, radiation protection, and other potential areas of concern," says Dr. Bertolatus, who also serves on the AAHRPP Council on Accreditation. "It's easy to coordinate all these activities when your IRB is overseeing the process. Once that's done by a distant IRB, things become more complicated on both ends."

Partly because of these complications, some IRBs are deciding not to oversee multisite reviews. "We were told the change would save time, but instead IRBs of record are facing a real challenge in managing the administrative burden and ensuring compliance," says Ms. (Petree) Mayo, Director of the Office of the IRB for The University of New Mexico. "Some are deciding against serving in that role, increasing the burden on others."

LINDA (PETREE) MAYO, CIP

Guidance, compliance, and other challenges

The transition to the new rule has been complicated, in part, by the absence of federal guidance on changes to continuing review, exempt research, and other updated provisions. "Many HRPPs have had to develop their own guidance, and that's problematic," Ms. (Petree) Mayo says. "The longer the delay in federal guidance, the greater the chance for inconsistencies."

To fill the gap, HRPPs have often turned to one another and to organizations such as AAHRPP and PRIM&R. AAHRPP and

What's Next for HRPPs? Experts Offer Insights (cont.)

PRIM&R have been addressing HRPPs' most frequent concerns via webinars and their respective annual **conferences,** and will continue to do so. The Collaborative AAHRPP Network (CAN), established last year, is another resource and source of support for accredited organizations. PRIM&R's Social Behavioral Education Research (SBER) Network serves in a similar role for those involved with SBER. Ms. (Petree) Mayo, a co-founder of the network, has seen an uptick in membership since the revised Common Rule was issued.

Looking beyond IRB review, our experts cite the challenges of emphasizing and ensuring adherence to the principles of responsible research. Some HRPPs have stepped up monitoring efforts. Our experts anticipate that others will follow and will increase the focus on researcher education.

Ethical concerns—such as protecting privacy in the age of big data and social media, and anticipating issues related to genomic research—also are expected to claim HRPPs' attention. "The potential advantages are huge," Dr. Bertolatus says, "but we need to be prepared for the challenges that might result."

*Note: All these issues, and more, are on the agenda of the 2020 AAHRPP **Annual Conference**, which will be held May 19-21 in Baltimore.*

Advocating for Patients and for AAHRPP

A cancer survivor and former clinical trial participant, Chris States holds a singular place on the AAHRPP Board of Directors. Mr. States is the patient advocate on a board where most members represent organizations that conduct or oversee research involving people who've been in his shoes.

Despite their different backgrounds, Mr. States and his AAHRPP colleagues have a common commitment to research participants, high-quality science, and ethical research. They also share a fundamental belief in the value of AAHRPP accreditation and a determination to continue to build on the organization's success.

CHRIS STATES

"We have a diverse board whose skills have enabled AAHRPP to grow as we have," he says. "We all play a similar role and have the same responsibilities to AAHRPP, accredited organizations and, above all, to research participants. As a former patient, I just bring a different perspective."

As an example, Mr. States cites his experience with informed consent years ago, when he participated in a clinical trial testing Marinol's effectiveness in treating chemotherapy-induced nausea and vomiting. The FDA has since approved the drug for that and other uses.

"When you're faced with a potentially terminal diagnosis, you're focused on the immediate issues of getting better and finding a cure," he says. "You have a tendency not to think of the long-term ramifications until later, and that affects your understanding during the informed consent process. You don't necessarily hear or comprehend all the information that's being presented."

The importance of high standards

Mr. States' views are also shaped by his professional experience as a biologist and senior environmental planner for the California Department of Transportation, a position that has fostered his appreciation for the role that regulators can play in setting and enforcing high standards.

He and his team perform the endangered species analyses that are integral to the permitting process. "What I've found is that the regulatory agencies govern very strictly," Mr. States says. "We are subject to the highest levels of scrutiny, and that has made us better biologists and better stewards of the environment.

"As a result, we set the standard for transportation and environmental projects," he adds. "Until you're involved in this type of effort, you don't realize the impact that high standards can have."

Mr. States joined the AAHRPP board in 2014 and takes pride in the organization's progress in the years since. He gives credit for AAHRPP's continued growth to his board colleagues, the AAHRPP team, and the leadership of Elyse I. Summers, JD, who has been president and CEO since October 2013.

"Elyse has done an excellent job in taking AAHRPP to the next level and setting the gold standard for research protection programs around the world," Mr. States says. "We are playing an important role within and outside the U.S., making sure the focus remains on ensuring the quality of the science and on protecting participants.

"The two go hand in hand," he adds. "If you're engaging in good science and providing full disclosure, patients can determine whether the benefits outweigh the risks—and can have confidence in their ability to make informed decisions."

Focusing on 'Challenge and Change'

Annual Conference May 19-21 in Baltimore

AAHRPP continues its tradition of using its Annual Conference to tackle some of the most pressing issues facing the research community. The 2020 event, "Challenge and Change in Charm City," will be held May 19-21 in Baltimore.

The Annual Conference has become a must-attend event for those involved in overseeing research, protecting research participants, and creating and sustaining high-quality HRPPs. The event features some of the most respected experts in the field.

This year's agenda includes:

- **Two pre-conference workshops**
  - Overview of AAHRPP for those who are new to accreditation or are preparing for reaccreditation.
  - Collaborative AAHRPP Network (CAN) forum for accredited organizations to network and discuss issues affecting research institutions.
- **Four thought-provoking plenary sessions**
  - Lessons Learned: Incorporating the Participant Perspective into Responsible Oversight and Use of Biospecimens.
  - Single IRB Check-In: Is It Working?
  - The Ethical, Regulatory, and Research Complexities of Human Gene Editing.
  - Data and Privacy in 2020.
- **Private screening of "Human Nature,"** an acclaimed documentary about CRISPR and the gene-editing tool's far-reaching complications.
- **30 breakout sessions**, covering topics including artificial intelligence, intercultural competence in transnational research, HRPPs and community health, vulnerable populations, and much more.
- **Poster presentations and networking opportunities.**

Registration is open.

Responding to Your Input on AAHRPP Reporting Requirements

AAHRPP has convened a working group to review our reporting requirements with an eye toward making them clearer and more manageable for our accredited organizations.

Reporting requirements have been in place since AAHRPP issued its accreditation standards in 2002 and historically have been included in our **Accreditation Procedures**. Because many organizations have been unaware of these requirements, to increase their visibility, in July we incorporated them in the **Evaluation Instrument**. We also added a requirement to inform AAHRPP about negative media reports.

Since then, we have received some questions. In keeping with our commitment to responsiveness, we created the working group and included representatives from a cross-section of the research community. In addition, as a demonstration of good faith, we are adopting the following practices while the working group review is underway:

- Step 1 reviewers will be advised that, until further notice, an organization's policies and procedures need not include the new Evaluation Instrument language regarding reporting; and
- In site visit reports and "off cycle" organizational reporting, AAHRPP will use its reasonable discretion in evaluating an organization's efforts to continue to report to AAHRPP under the existing Accreditation Procedures, including the request within the Accreditation Procedures to seek AAHRPP's guidance in areas of doubt regarding reporting.

From the President and CEO

2019: A Year of Accomplishments as Partner, Educator, Convener, and Resource

ELYSE I. SUMMERS, JD

By any measure, 2019 was a successful year for AAHRPP. We welcomed 10 more accredited organizations, including our first institution in Jordan, first entity affiliated with a major health insurer, and third U.S. federal department. Equally important, we continued to nurture relationships across the research enterprise in service of our long-term goal of protecting research participants by achieving one standard worldwide for high-quality ethical research.

With each year, we strengthen AAHRPP's reputation not only as an international accrediting body but also as a partner, educator, convener, and resource for those who share our commitment to safeguarding the participants who help make research possible.

Highlights from 2019 include:

- **Sharing our expertise:** Senior staff joined colleagues from across the research enterprise, presenting at conferences, serving on steering committees, participating in panel discussions and webinars, and taking advantage of other opportunities to shape key conversations about research protections. AAHRPP was well-represented at the PRIM&R 2019 Advancing Ethical Research Conference, Multi-Regional Clinical Trials (MRCT) Center 2019 Annual Meeting, Society of Clinical Research Associates (SOCRA) 2019 Annual Conference, and the Annual Virginia IRB Consortium Conference.

- **Educating and informing:** AAHRPP hosted "getting started" webinars for those interested in pursuing accreditation as well as educational webinars on hot topics facing HRPPs and research organizations. We also took our accreditation message to China and Korea and educated individuals around the world about the vital role of a robust HRPP in ensuring protections for research participants.

- **Showcasing "Big Ideas and Ethics in the Big Easy":** The 2019 AAHRPP Annual Conference drew nearly 500 attendees from nine countries to New Orleans to learn more about AAHRPP accreditation, get the latest information on the new Common Rule and other pressing issues, and network with colleagues from around the globe.

- **Fostering collaboration:** Our Annual Conference also provided the ideal venue to launch the Collaborative AAHRPP Network (CAN), a forum where members of accredited organizations could discuss issues, brainstorm, and share insights. As we did last year, we will feature a full day of programming for CAN members at a special pre-conference workshop this May.

- **Increasing diversity:** We expanded our pool of site visitors, adding individuals whose backgrounds and geographic locations reflect our increasingly diverse accredited organizations and applicants.

Looking ahead

AAHRPP expects 2020 to bring further progress in enhancing research protections and advancing new, innovative research. In keeping with our commitment to continuous improvement, we will seek additional ways to meet your needs and make the accreditation experience even better. We know, for example, that many of you would prefer an online submission and accreditation management system—and we look forward to getting your input on how to best meet your needs.

We have a fascinating **conference** planned for May 19-21 in Baltimore and, through our outreach and education efforts, we will remain a go-to resource on HRPP-related issues. We also will continue our steady march—across the research enterprise and around the globe—to strengthen research protections one accreditation at a time.

From the President and CEO (cont.)

Success is a joint effort, and I can say without hesitation that AAHRPP has an all-star team. It started back in 2001, with the seven visionary organizations that became our **founding members**: the Association of American Medical Colleges (AAMC), Association of American Universities (AAU), Association of Public and Land-grant Universities (APLU), Consortium of Social Science Associations (COSSA), Federation of American Societies for Experimental Biology (FASEB), National Health Council, and Public Responsibility in Medicine and Research (PRIM&R). Since then, we've benefited from the dedication and skill of extraordinary individuals who have served on our Board of Directors and Council on Accreditation and as site visitors. We have had—and continue to have—exceptional staff, and we are gratified by the support we receive from so many partners throughout the research community.

Of course, the coming years will bring their share of challenges. But with you and others on our team, we face those challenges—and the future—with confidence.

Thank you!

Elyse I. Summers, JD
AAHRPP President and CEO