

AAHRPP ADVANCE

One Standard Worldwide

FALL 2018

Introducing the Collaborative AAHRPP Network

The Collaborative AAHRPP Network (CAN) will make its debut in May at the 2019 AAHRPP Conference in New Orleans. For the first time, the pre-conference day—previously devoted exclusively to helping those pursuing accreditation or reaccreditation—will feature a second option: a full day of additional programming for interested accredited organizations. [LEARN MORE](#)

AEREO Focuses on HRPP, IRB Effectiveness



The new Consortium to Advance Effective Research Ethics Oversight (AEREO) seeks to evaluate and improve HRPPs and IRBs. Accredited organizations can use AEREO activities to fulfill AAHRPP requirements for continuous quality improvement. [LEARN MORE](#)

Reporting Requirements Keep All Better Informed

Under new reporting requirements, accredited organizations will be asked to notify AAHRPP within 48 hours of learning about negative media coverage related to human research protection issues. [LEARN MORE](#)

From the President and CEO



AAHRPP President and CEO Elyse I. Summers, JD, highlights AAHRPP's longstanding emphasis on quality and collaboration. Two new initiatives demonstrate a continued commitment to partner to strengthen human research protections and advance ethical research. [LEARN MORE](#)

Save The Date

2019 AAHRPP Conference: May 21–23 at the Ritz Carlton, New Orleans

FALL 2018

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IN BRIEF

Evaluation Instrument Gets New Look. Check out our redesigned [Evaluation Instrument](#). The fresh, new look makes it easier to find the information you need.

AAHRPP in Asia. In response to increased interest in accreditation, AAHRPP will host two educational events in China in January. Each program will include sessions on the accreditation process and AAHRPP standards, and will include opportunities for interested organizations to meet one-on-one with AAHRPP team members.

Addenda Additions. AAHRPP has published two new international addenda, for Jordan and South Africa. Both are posted on the AAHRPP [website](#).

'CAN' Project Offers Forum for Accredited Organizations

AAHRPP-accredited organizations will soon have a new forum where they can discuss issues, brainstorm, and share insights on accreditation and the changing research environment.

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The goal is to strengthen connections and foster collaboration in a collegial, peer-to-peer setting.

“We envision a different kind of forum, not a formal conference but a place where people can share ideas and raise issues in a more informal, collaborative manner,” says Michele Russell-Einhorn, JD, Chief Compliance Officer and Institutional Official, Advarra.

She and Martha Jones, MA, CIP, Executive Director, Human Research Protection Office, Washington University in St. Louis, approached AAHRPP about establishing the CAN and, in collaboration with AAHRPP senior staff, are spearheading the effort. Both are AAHRPP site visitors. In addition, Jones serves as vice chair of AAHRPP’s Council on Accreditation.



**MICHELE
RUSSELL-EINHORN, JD**

Russell-Einhorn and Jones also are members of the National Comprehensive Cancer Network (NCCN) IRB Directors Forum, which they view as a model for the CAN. Much like NCCN members, representatives of AAHRPP-accredited organizations have common experiences and expertise, and can benefit from sharing both.

“You have a group of organizations that follow the same standards, have similar policies and practices, and face similar concerns,” Russell-Einhorn says. “Why not bring them together to learn from one another?”



**MARTHA JONES,
MA, CIP**

Jones sees the CAN as an opportunity for AAHRPP to take the lead in addressing an unmet need. “A lot of organizations don’t have access to a community of colleagues they can turn to on accreditation and research protection issues,” she says. “This is a way for AAHRPP to fill that void—to create a great program that encourages organizations to tap AAHRPP’s resources in between accreditation cycles.

“Achieving accreditation is just one of our goals,” Jones adds. “Accreditation is also an ongoing process to make sure we’re doing everything we can to have an effective HRPP. Any time you can collaborate with your colleagues, you can continue to identify and adopt best practices.”

The timing couldn’t be better. The CAN will provide an ideal forum for members of accredited organizations to discuss different approaches to the revised Common Rule and other topics of concern. The CAN will also serve as a vehicle to provide input on areas that AAHRPP could target for improvement.

“We are constantly looking for feedback from people in the field on challenges they face in meeting our standards and responding to changes in the research community,” says Michelle Feige, MSW, LCSW-C, Executive Vice President, AAHRPP. “The CAN is an exciting collaboration, and we encourage accredited organizations to participate.”

AAHRPP will reach out to accredited organizations before the 2019 conference to provide additional details and solicit suggestions on CAN topics. Watch for more information in the coming weeks.

Consortium Seeks to Evaluate, Enhance HRPP Effectiveness

AEREO activities can be used to meet AAHRPP accreditation standard

What are the outcomes of an effective HRPP? Can they be empirically evaluated—and, if so, can that data help drive best practices?

Those are just some of the questions being tackled by the Consortium to Advance Effective Research Ethics Oversight (AEREO), a project launched in May that is bringing experts in human research protections together to help assess and improve human research protection programs (HRPPs) and institutional review boards (IRBs).

AEREO is the brainchild of Holly Fernandez Lynch, JD, MBE, an academic attorney-bioethicist and the John Russell Dickson, MD, Presidential Assistant Professor of Medical Ethics at the University of Pennsylvania's Perelman School of Medicine. Her research seeks to evaluate how well HRPPs and IRBs achieve their ethical objectives, and to identify ways to improve HRPP and IRB effectiveness.

About a year ago, Fernandez Lynch began reaching out to experts throughout the HRPP community. Twenty-seven colleagues from some of the nation's most respected academic, healthcare, and government institutions and independent IRBs joined her as founding members of AEREO. AAHRPP gave the effort a boost by permitting accredited organizations to use participation in AEREO activities to meet accreditation Standard 1-5, Element 1.5.B, which requires organizations to demonstrate continuous quality improvement.

"AAHRPP and AEREO share a commitment to identifying and supporting effective, innovative systems of protecting research participants," says AAHRPP President and CEO Elyse I. Summer. "It's only natural that we would collaborate and encourage our accredited organizations to do so, as well."

Finding new means of assessment

The issues that AEREO seeks to address have presented challenges to the research ethics community for decades, in part because the benefits of strong HRPPs can be difficult to

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EARLY AEREO COLLABORATORS

Members of the new Consortium to Advance Effective Research Ethics Oversight (AEREO) include:

Steering Committee*

Holly Fernandez Lynch, JD, University of Pennsylvania Perelman School of Medicine, *Co-Chair*

Holly Taylor, PhD, Johns Hopkins University, *Co-Chair*

Steven Joffe, MD, University of Pennsylvania Perelman School of Medicine

Susan Kornetsky, PhD, Boston Children's Hospital

Megan Kasimatis Singleton, JD, Johns Hopkins University School of Medicine

Tracy Ziolek, University of Pennsylvania

Consortium Members*

Barbara Bierer, MD, Harvard Medical School, Brigham & Women's Hospital

Justin Clapp, PhD, University of Pennsylvania

Carl Coleman, JD, Seton Hall University School of Law

Whitney Eriksen, PhD, University of Pennsylvania

Eric Garcia, Kaiser Permanente

Richard Gorman, MD (retired)

Christine Grady, PhD, NIH

Jonathan Green, MD, NIH

Sarah Greene, Health Care Systems Research Network

Karen Hansen, Fred Hutchinson Cancer Research Center

Elisa Hurley, Public Responsibility in Medicine & Research (PRIM&R)

Karen Jeans, PhD, Department of Veterans Affairs

Lisa M. Lee, PhD, Virginia Polytechnic Institute and State University

Lindsay McNair, MD, WIRB-Copernicus Group

Michelle N. Meyer, PhD, JD, Geisinger Health System

Stuart Nicholls, PhD, Ottawa Hospital Research Institute

Linda Parecco, RN, National Cancer Institute

Suzanne M. Rivera, PhD, Case Western Reserve University

Stephen Rosenfeld, MD, Quorum IRB

Michele Russell-Einhorn, JD, Advarra

Ada Sue Selwitz, University of Kentucky

David Strauss, MD, Columbia University, Austen Riggs Center

*Participate in individual, not institutional, capacity.

Consortium Seeks to Evaluate, Enhance HRPP Effectiveness (cont.)

quantify. As a result, evaluations of HRPPs and IRBs tend to focus on process and structure instead of outcomes.

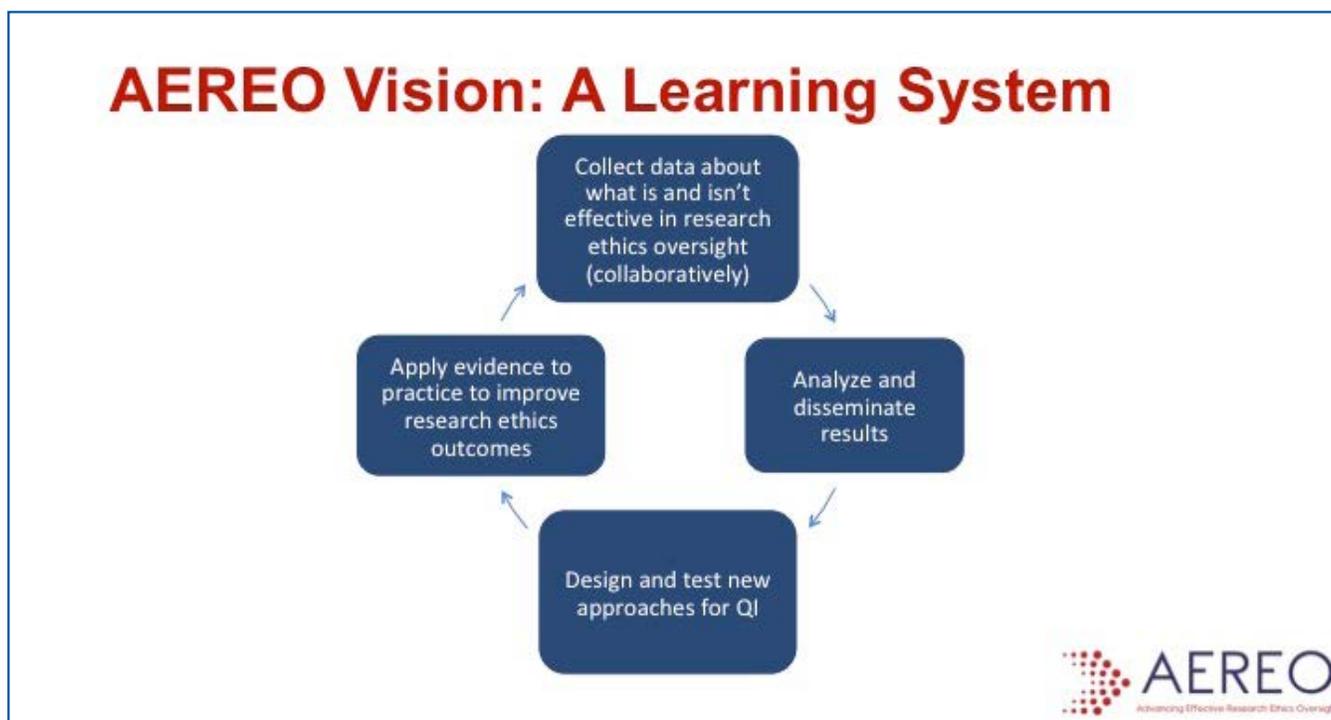
“We can collect data on regulatory compliance, turnaround time, and IRB composition, but that doesn’t really evaluate effectiveness—whether HRPPs and IRBs are accomplishing what they were created to do,” Fernandez Lynch says. “How do we measure, for example, whether an HRPP is really protecting participants, building trust, and creating a culture of ethics and justice?”

“When we evaluate drugs and other medical interventions, we don’t just look at how they were made. We consider their impact on patients,” she adds. “We need to find a way to apply that same level of evidence-based review to HRPPs and IRBs.”

The current increased emphasis on evidence-based policy is one reason Fernandez Lynch believes the time is right for AEREO. She also points to regulatory changes—including the shift to single-IRB review and other revisions to the Common Rule—as indications that the research ethics community should support empirical approaches to evaluating HRPPs to help ensure protections while reducing inefficiencies.

AEREO will start by asking stakeholders—research participants, IRB members, sponsors, researchers, etc.—what they expect from HRPPs and whether those expectations are being met. The consortium also will seek to address barriers to empirical research on HRPP effectiveness and identify meaningful assessment methods.

The long-term goal is to develop a learning system that supports ongoing evaluation and improvement.



AAHRPP’s supporting role

From the beginning, AAHRPP has required accredited organizations to view protecting research participants as a responsibility that is shared by the entire institution, not just the IRB. That requirement played a key role in the development of today’s comprehensive HRPPs.

AAHRPP’s high standards for research ethics and protections have helped raise the bar for accredited and not-yet-accredited organizations around the globe. It is fitting, then, that AAHRPP supports new efforts to further that work by evaluating HRPPs with an eye toward further improvement.

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Consortium Seeks to Evaluate, Enhance HRPP Effectiveness (cont.)

“We see AEREO as providing an opportunity to take research protections and processes to the next level, and we want to be part of that,” Summers says.

AAHRPP’s involvement reflects the accrediting body’s increased emphasis on flexibility and collaboration.

“AAHRPP sets the standard, but does not prescribe that it be met in a specific way. We leave it to each organization to decide what works best,” Summers explains. “Now, participating in AEREO research will be one of many ways that accredited

organizations can meet the AAHRPP standard for quality improvement.”

As for collaboration, working with AEREO will be yet another example of AAHRPP living up to its commitment to partner to encourage effective, efficient, and innovative systems of protection for human research participants worldwide.

For more information on AEREO, contact [Holly Fernandez Lynch](#).

Updated Reporting Requirements

AAHRPP is updating our reporting requirements to ensure that we receive timely notification when an accredited human research protection program (HRPP) becomes aware of negative findings by a government oversight office, legal action related to human research protections, or unfavorable media coverage.

The updated language—for Standard 1-5, Element 1.5.D—has been incorporated into our [Evaluation Instrument](#) and will read as follows:

Element 1.5.D.: The organization has and follows written policies and procedures for addressing allegations and findings of non-compliance with Human Research Protection Program requirements. The organization works with the Institutional Review Board or Ethics Committee, when appropriate, to ensure that participants are protected when non-compliance occurs. Such policies and procedures include reporting these actions, when appropriate.

New requirement under Element 1.5.D. located at (1)(h): Policies and procedures describe the reporting to AAHRPP as soon as possible but generally within 48 hours after the organization or any researcher (if

the researcher is notified rather than the organization) becomes aware of:

- (i) Any negative actions by a government oversight office, including, but not limited to, OHRP Determination Letters, FDA Warning Letters, FDA 483 Inspection Reports with official action indicated, FDA Restrictions Placed on IRBs or Investigators, and corresponding compliance actions taken under non-US authorities related to human research protections
- (ii) Any litigation, arbitration, or settlements initiated related to human research protections
- (iii) Any press coverage (including but not limited to radio, TV, newspaper, online publications) of a negative nature regarding the organization’s HRPP

“It’s important that we are aware, in real time, of issues affecting our accredited organizations,” AAHRPP President and CEO Elyse I. Summers, JD, says. “These updates will help keep us in the loop.”

AAHRPP will provide training on the updated requirements, and will provide additional information soon.

Sharing Staff Expertise

If you're attending the **Public Responsibility in Medicine and Research (PRIM&R)** conference next month, you'll have several opportunities to see the AAHRPP team in action.

Thursday, November 15:

Michelle M. Feige, MSW, LCSW-C, AAHRPP Executive Vice President, will be one of three presenters at a session on "Defining Roles & Expectations for the Non-Scientist and Non-Affiliated IRB Member: Deconstructing Regulatory and Research Terminology." Feige is also one of two co-chairs for the Workshop and Didactic Subcommittee, which plans the conference breakout sessions.

Robert Hood, PhD, AAHRPP Director of Accreditation, will be one of two presenters on "An Educational Map to Being a Great Research Ethicist (or Just a Better One)."

Saturday, November 17:

"A Dialogue with AAHRPP" will feature Elyse I. Summers, JD, President and CEO; Feige; Dr. Hood;

Lori Kravchick, Office Manager; and Kate Vulakovich, Assistant Director of Accreditation.

Senior staff also shared their expertise during conferences in September:

At the **Society of Clinical Research Associates (SOCRA)**:

- Summers and Feige presented "Methods Establishing a High-Quality Human Research Protection Program (HRPP): the AAHRPP Model."
- Feige was a panelist for "Methods Centralized IRB Review of Multi-Site Clinical Research. Do you have Single/Central IRB questions? Ask the panel of experts."

At the **National Institutes of Health (NIH)**:

- Summers moderated a panel during the Single IRB Review for Multi-Site Research: Resource and Infrastructure Development Workshop.



Save the Date:
May 21-23, 2019

Ritz Carlton
New Orleans

Join us for
*"Big Ideas and Ethics
in The Big Easy"*



2019 AAHRPP Annual Conference

From the President and CEO

Getting even better together

Quality and collaboration are recurring themes at AAHRPP.

As most of you know, AAHRPP's founding—by the Association of American Medical Colleges, Association of American Universities, Association of Public and Land-grant Universities, Consortium of Social Science Associations, Federation of American Societies for Experimental Biology, National Health Council, and Public Responsibility in Medicine & Research—was a collaborative effort to strengthen human research protections and improve the quality of research. We have been building on that foundation ever since by emphasizing partnerships, requiring AAHRPP-accredited organizations to commit to continuous quality improvement, and demanding that same commitment of ourselves.

In this issue of *Advance*, we highlight two innovative, quality-related partnerships and encourage you to join us in embracing them.

Our new Collaborative AAHRPP Network (CAN) will bring accredited organizations together to share perspectives, strengthen relationships, and benefit from one another's expertise. If you have questions or concerns about issues related to human research protections, chances are some of your colleagues do, too. Why not work together and draw on each other's experiences to find solutions—and to make AAHRPP aware of ways that we can help? We will launch the CAN in May as part of our 2019 conference.

The second initiative, the Consortium to Advance Effective Research Ethics Oversight (AEREO), seeks to assess and improve HRPPs and IRBs—goals that are near and dear to AAHRPP. Therefore, accredited organizations that participate in AEREO activities may use them to meet AAHRPP's standards on continuous quality improvement. We are confident that the research community can benefit enormously from the insights and practices of AAHRPP-accredited organizations.



ELYSE I. SUMMERS, JD

I also draw your attention to a change in our reporting requirements. Historically, AAHRPP organizations have done an excellent job keeping us informed of compliance-related actions by government offices and litigation related to human research protections. Now, we're asking you to also notify us of any negative media coverage related to your HRPP. It's one more way we can stay on top of potential quality concerns.

Finally, I ask you to mark your calendars for the 2019 AAHRPP conference, Big Ideas and Ethics in The Big Easy, which will be held May 21-23 in New Orleans. Our new CAN program will make its debut as part of our pre-conference programming. I can't think of a better reason to spend another day together.

A handwritten signature in blue ink that reads "Elyse I. Summers". The signature is fluid and cursive, with a long horizontal stroke at the end.

Elyse I. Summers, JD
AAHRPP President and CEO