

AAHRPP ADVANCE

One Standard Worldwide

FALL 2021

From the President and CEO

President and CEO Elyse I. Summers, JD, provides a glimpse of the benefits organizations can expect when AAHRPP launches its new website and online accreditation management system (OAMS) next year. [LEARN MORE](#)

On the Front Line of COVID-19 Vaccine Clinical Trials

Longtime AAHRPP team leader and site visitor Robert Frenck, MD, and his team at Cincinnati Children's Hospital Medical Division helped evaluate COVID-19 vaccines for adults and for children under 12. [LEARN MORE](#)

IRBs' Role in Achieving Diversity, Inclusion, and Justice

An MRCT guidance document and *Science Magazine* article call on IRBs to help take the lead in advancing and assessing efforts to promote diversity, inclusion, and equity in clinical research. [LEARN MORE](#)

AEREO: Progress on Advancing IRB Effectiveness

In the three years since its founding, the Consortium to Advance Effective Research Ethics Oversight (AEREO) has been making steady progress in its efforts to change how the human research protection community frames and evaluates IRB success. [LEARN MORE](#)

Reminder: Health Literacy Webinar November 9

There's still time to [register](#) for our upcoming webinar. "Health Literacy Resources to Strengthen Your Human Research Protection Program" will be held November 9 from 1:00-2:30 p.m. ET. Registration is free for AAHRPP-accredited organizations; \$90 for those not-yet-accredited. The deadline to register is November 7.

FALL 2021

INSIDE

2 From the President & CEO

3 At the Forefront of COVID-19 Vaccine Trials

4 Achieving Diversity and Justice in Research

6 Advancing IRB Effectiveness

NEWS & NOTES

- AAHRPP introduces [element](#) on emergency preparedness.
- [2020 metrics](#) for HRPP performance now available.
- AAHRPP Executive Vice President Michelle Feige, MSW, LCSW-C, earns Certificate in Diversity and Inclusion.
- [Check out AAHRPP sessions](#) at PRIM&R November 16-19.
- 2022 AAHRPP Annual Conference: May 24-26 in Denver.

From the President and CEO

Coming Soon: Our Updated Website and First Online Accreditation Management System

I am excited to share that you'll soon be enjoying a more user-friendly experience at www.aahrpp.org, including our first online accreditation management system (OAMS). Our updated website will debut by mid-year 2022. We will follow that with a phased-in rollout of our OAMS, starting with a pilot program by early 2023.

Both initiatives reflect significant investments to enhance the ease and efficiency of the accreditation process and strengthen AAHRPP's relationships with our stakeholders. We want to make it as simple as possible for people to turn to AAHRPP—with questions, for helpful resources, and to apply for accreditation or reaccreditation.

The website redesign is based on the input of board members, site visitors, AAHRPP staff, and members of all AAHRPP constituencies. As a result, you can expect a more intuitive website, with an enhanced search function and a more modern design and organizational structure. Much of the information will be available to anyone who wants the latest news about AAHRPP, information on best practices for human research protection programs (HRPPs), and updates on important research protections issues.

Equally impressive, if not more so, are the secure features—especially the OAMS—that will be reserved for AAHRPP-accredited organizations and those in the midst of the accreditation process. Our OAMS will be your one-stop shop for all things related to your accreditation or reaccreditation application. Sign in and:

- You will be able to work on your application, save your progress, and return later to pick up where you left off.
- Your documents will be easy to find and access.
- If you're seeking reaccreditation, fields for information already on file with AAHRPP will be pre-populated.
- A personalized dashboard will make it easy to track your progress. With one glance, you will know which sections of your application are complete, the tasks that remain, and their due dates.



ELYSE I. SUMMERS, JD

We will provide more information, including education on the OAMS, as we get closer to the launch dates.

The website redesign and OAMS addition have been massive undertakings. The projects also reminded us of what it means to be part of such a collegial, collaborative community. We are grateful to everyone who made the time to provide feedback on our existing website and share what they'd most like to see in an OAMS.

AAHRPP has always prided itself on being an invaluable source of information. Soon, because of so many of you, that information will be more accessible, more digestible—and more impactful.

With appreciation,

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

Building Trust One Shot at a Time

Food and Drug Administration (FDA) advisers' decision to authorize the first COVID-19 vaccine for young children was based, in part, on data from clinical trials conducted by longtime AAHRPP team leader and site visitor Robert Frenck, MD, and his team at Cincinnati Children's Hospital Medical Division.



Dr. Frenck is director of the Gamble Center for Clinical Research at Cincinnati Children's and principal investigator of the hospital's Vaccine Treatment and Evaluation Unit (VTEU). The VTEU is one of five nationwide chosen to help do the initial testing and evaluation of the Pfizer-BioNTech COVID-19 vaccine for children under 12.

The VTEU also has helped assess the AstraZeneca and Pfizer vaccines for adults and, most recently, the Moderna COVID-19 vaccine for pediatric use.

For much of the pandemic, Dr. Frenck's team worked on-site 60 to 70 hours per week, risking potential coronavirus exposure while "under a microscope every minute. People were nervous, but they put their concerns aside because this is what we trained for. This is our job," Dr. Frenck says. "In the end, they made history. They've been amazing, and I couldn't be prouder."

The pressure was greater than at any other time in Dr. Frenck's more-than-20-year career in vaccine research. "We were watching the world burn, knowing that people were counting on us for vaccine results and hoping for efficacy rates of at least 50% to 60%," he says.

In November 2020, Dr. Frenck got the call from Pfizer. The results were in and—at 95% efficacy—had exceeded all expectations. "It literally felt like a 10,000-pound weight was lifted off my shoulders," he says. "All the work had been worth it."

Pandemic Highs and Lows

That call is at or near the top of Dr. Frenck's list of pandemic high points. Also up there are nurses at Cincinnati Children's who were furloughed from their ICU assignments and stepped up to join his vaccine team. Some have since chosen to pursue careers in research.

Individuals, including adolescents and children, who volunteered for his vaccine trials rank high as well. Dr. Frenck speaks of young children who dressed up for the occasion, including a 3-year-old girl who beamed as she announced, "I'm here for my COVID vaccine." Dr. Frenck's response: "Good for you!"

Adolescent volunteers impressed him with their enthusiasm and conviction. Almost uniformly, they gave the same answer when he asked why they chose to participate: "If not me, who?" Members of minority populations cited the importance of demonstrating the vaccine's safety to others in their communities. "Obviously, they wanted to protect themselves," Dr. Frenck says, "but their primary motivation was to help society."

On the other hand, vaccine resistance remains a source of frustration, especially "when you work as hard as people have and come up with products as effective as these vaccines. We have a way to stop this pandemic, if only people would get the vaccine."

If he could deliver just one message, Dr. Frenck would focus on vaccine safety. And that's exactly what he does in meetings, presentations, and while out in the community, addressing individuals' concerns one on one while offering them the opportunity to get vaccinated.

"All of these studies were conducted at the highest level, and all regulations were followed. It's important that we make the community aware of this," he says. "I am going to keep soldiering on, meeting with people and showing them the data."

A Matter of Trust

As a pediatrician and professor of pediatrics, Dr. Frenck has seen vaccine hesitancy before but not at the current level. He attributes the intensity both to the highly charged political environment and the need for mass vaccination to fight the pandemic. The situation "has been amplified because you're asking everyone to get vaccinated at the same time," he explains.

His solution is rooted in his long-term belief in the importance of building trust—in vaccine development and research in general. That's one reason Dr. Frenck has been an AAHRPP site visitor since 2007. "We owe the community an assurance that research is being conducted in accordance with the highest standards," he says, "and AAHRPP accreditation helps provide that."

IRBs Can Play Pivotal Role in Achieving Diversity and Justice in Research

As the research community grapples with addressing the lack of diversity, inclusion, and equity in clinical research, IRBs have the responsibility and authority to play a lead role in advancing these efforts. IRBs are uniquely positioned to require information on inclusion in protocol descriptions and to assess study documents for inclusion “across all relevant dimensions of diversity.”

Those are among the conclusions of “Achieving Diversity, Inclusion, and Equity in Clinical Research,” a comprehensive **guidance** document issued by the Multi-Regional Clinical Trials Center of Brigham and Women’s Hospital and Harvard (MRCT Center).

The MRCT Center is a research and policy center focused on addressing the conduct, oversight, ethics, and regulatory environment for clinical trials. Authors of the guidance document are Barbara E. Bierer, MD, MRCT Center Faculty Director and Professor of Medicine, Harvard Medical School; Sarah A. White, MPH, MRCT Center Executive Director; Laura G. Meloney, MPH, MS, and Hayat R. Ahmed, MS, MRCT Center Program Managers; David H. Strauss, MD, MRCT Senior Advisor and Special Lecturer, Columbia University; and Luther T. Clark, MD, Deputy Chief Patient Officer, Merck & Co.

The MRCT Center guidance was developed by a workgroup of more than 50 members representing stakeholders across the global research enterprise. Although the group was established before COVID-19, their efforts took on new urgency after the pandemic shined a spotlight on dramatic disparities in health and on institutional racism in the U.S.

“This moment is a—long delayed—call to action,” wrote Dr. Bierer in the guidance document author’s note. “Eliminating racism and racial inequalities begins with eliminating disparities in health, and that necessarily demands deliberate and purposeful inclusion in health research that itself will help lead to equitable access and outcomes.”

The MRCT Center guidance makes the case for diversity in clinical research, identifies barriers to inclusion, and presents potential approaches and solutions. A separate **toolkit** provides logic models, engagement strategies, checklists, and other resources to help sponsors, investigators, IRBs, and others involved in research increase diversity in clinical trials.

While it acknowledges that achieving representativeness in clinical research must be a collaborative effort, the guidance also argues that IRBs have the authority to make diversity and inclusion provisions an expectation for study approval. The ethical and historical basis for this IRB responsibility is discussed in “Justice, diversity, and research ethics review,” co-authored by three MRCT Center Diversity Workgroup members and published in the March 19, 2021, issue of *Science Magazine*.

The authors—Dr. Strauss, Ms. White, and Dr. Bierer—cite the Belmont Report, World Health Organization’s International Ethical Guidelines for Health-related Research Involving Humans, and World Medical Association Declaration of Helsinki in concluding that “consideration of diversity is essential to the question of fairness in subject selection and to IRB review.” They urge IRBs to look “beyond the lens of ‘protection,’ to deliberate on the benefits and risks of greater inclusion, and to exercise their authority to promote diversity ... as a matter of justice.”

Recommendations for IRBs

The MRCT Center guidance acknowledges the challenges of adding expectations for IRB reviews and offers recommendations for IRBs to consider as they take on this expanded role. For example, IRBs should:

- Include representatives of local underserved and minority communities as members of the IRB.
- Provide training to IRB members and administrators on implicit bias and cultural competence.
- Require investigators to provide demographic characteristics of the proposed study sample as well as a feasibility plan based on the local community at the time of initial IRB review. At continuing review, IRBs should compare participant demographics to the goals in the feasibility plan and request remediation if necessary.



IRBs Can Play Pivotal Role in Achieving Diversity and Justice in Research

- Designate a member of the IRB to act as a “patient representative,” responsible for ensuring patient, public, and community input; diverse representation; easily understandable (and translated if necessary) consent and other documents; and other measures to meet the needs of underrepresented populations.
- Revise policies, procedures, education requirements, and tools and checklists to incorporate review and oversight of diversity and inclusion in research at initial and continuing review.

Dr. Bierer views the expanded role of IRBs as a supportive one. “We’re not suggesting that IRBs need to act in a punitive way,” she says. Instead, they could ask questions about how a lack of diversity might limit the ability to generalize results. IRBs also could offer to help principal investigators with tasks such as translating documents and creating health-literate resources for participants.

At the same time, IRBs must be able to count on the cooperation and commitment of others. “One of the critical points is that the

IRB is not acting alone,” Dr. Bierer says. “To do this work well—to assist principal investigators and their study teams—IRBs will need the support of their institutions.”

She gives a nod to the individuals and organizations, including AAHRPP, whose contributions helped make the guidance document and toolkit possible. Dr. Bierer notes AAHRPP’s assistance in developing tools and resources and providing an understanding on what lies within and beyond the scope of IRB responsibility.

Like the workgroup, “AAHRPP and the institutions it accredits want to see a future that is better than today,” Dr. Bierer says, “one that protects human participants, includes diverse populations in research, and advances science that can help create and implement data-driven, impactful solutions.”

Save the Date: May 24-26, 2022



**2022 AAHRPP
Annual Conference**

**in Denver, Colorado
May 24-26, 2022**

**Mark your calendars for one of the research
community’s must-attend annual events.**



In the three years since its founding, the Consortium to Advance Effective Research Ethics Oversight ([AEREO](#)) has been making steady progress in its efforts to change how the human research protection community frames and evaluates IRB success.

AEREO now has more than 70 members—from over 50 organizations, institutions, and agencies—who share a common goal of designing more meaningful ways to define and measure “what it means for an IRB to perform at an optimal level,” says Holly Taylor, PhD, MPH, who co-chairs AEREO with Holly Fernandez Lynch, JD, MBe.

Dr. Taylor is a research bioethicist in the Department of Bioethics at the Clinical Center, National Institutes of Health. Ms. Fernandez Lynch is the John Russell Dickson, MD, Presidential Assistant Professor of Medical Ethics at the University of Pennsylvania.

IRB quality traditionally has been linked to process- and burden-related metrics—such as cost and turnaround times—in part because they are easy to quantify. AEREO has taken on the bigger challenge of determining whether and how well human research protection programs (HRPPs) and IRBs achieve more qualitative goals around effectiveness, including:

- Protecting research participants.
- Promoting justice in research.
- Creating a culture of ethical concern among research stakeholders.
- Establishing public trust in the research enterprise.
- Ensuring socially valuable, scientifically valid, ethical research.

“If we’re assessing the value and quality of IRB review, we have to look at the benefits as well as the burdens,” Ms. Fernandez Lynch says. “We have to focus on outcomes, especially for research participants.”

Ultimately, AEREO would like to design methods to help IRBs and HRPPs better assess and improve outcomes. To achieve that long-term objective, the consortium has begun compiling and analyzing descriptive data, interviewing and surveying stakeholders, and testing interventions and approaches—all with an eye toward developing recommendations for best practices and policies.

Five Priorities

The consortium’s early research has confirmed both the need for more qualitative assessments of IRB effectiveness and the difficulties of conducting these assessments. Two recent [projects](#)—a review of

10 quality assessment instruments and an analysis of how AEREO members meet the key information requirement of the 2019 Common Rule—found wide variability in IRB approaches. One area of consistency: Existing assessment instruments emphasized process and structure over outcomes.

To shift that emphasis, AEREO is targeting five priorities:

- Stakeholder perceptions on the value of IRBs.
- Patient and participant goals and expectations of IRB review.
- Participant outcomes and ways IRB oversight might influence those outcomes.
- IRB deliberations and discretion.
- Processes and structures likely linked to participant protection.

“What we are focused on is a more qualitative analysis of what it means for IRBs to do a good job,” Ms. Fernandez Lynch says.

How AEREO’s priorities are addressed will be up to its members.

“We really rely on them to bring ideas to the table and use AEREO as a launching pad,” Dr. Taylor says. “We have the capacity to advance our members’ ideas and take what might otherwise be a fairly limited project and help turn it into something powerful.”

An Ally and Partner

She and Ms. Fernandez Lynch stress that AEREO is an ally to IRBs and HRPPs, with members drawn from key leaders in this community. “We are not here to point out what IRBs and HRPPs are not doing,” Ms. Fernandez Lynch says. “If there are areas where we need to improve, we are here to move that forward in a friendly, collaborative way—to work together to protect participants and enable high-quality, ethical research to advance.”

AEREO also has a partner in AAHRPP, which permits organizations to use participation in certain AEREO activities to meet accreditation requirements to demonstrate continuous quality improvement. AAHRPP will also be distributing a survey among accredited organizations as part of an AEREO research project focused on the role of lay members. The collaboration is a natural extension of both organizations’ commitment to advance high-quality research and protect the participants who make it possible.

More information about the consortium, including how to become a member, is available on the [AEREO website](#).

News & Notes

New element I.1.H on emergency preparedness: Our new element requires organizations to have policies and procedures in place to protect research participants in an emergency. You can find the documentation [here](#).

Latest metrics: AAHRPP's **2020 metrics** for HRPP performance are now available to help stakeholders identify and support best HRPP practices.

Diversity and inclusion: AAHRPP Executive Vice President Michelle Feige, MSW, LCSW-C, has earned a Certificate in Diversity and Inclusion from Cornell University. Courses covered topics including improving engagement, counteracting unconscious bias, and diversity and inclusion at work.

Look for us at PRIM&R's virtual conference: The AAHRPP team is participating in PRIM&R's upcoming Advancing Ethical Research (AER21) Conference. Tune in for these sessions:

- **November 16, 2:30-5:30 p.m. ET, Pre-Conference Session: Crossing Borders: HRPPs and Protection of Subjects in Transnational Research;** presenters include AAHRPP's Nichelle Cobb, PhD.
- **November 17, 11:45 a.m.-12:45 p.m. ET, Beyond Reliance Agreements: Local Considerations, Risk Mitigation, and Compliance;** presenters include AAHRPP's Nichelle Cobb, PhD.
- **November 17, 1:45-2:45 p.m. ET, A Dialogue With AAHRPP, Inc.,** featuring Elyse Summers, JD; Michelle Feige, MSW, LCSW-C; Robert Hood, PhD; Nichelle Cobb, PhD; and Kate Vulakovich, CCRP.
- **November 17-19, AAHRPP Virtual Booth.** Video chat with AAHRPP staff members during our lunchtime office hours each day.
- **November 18, 1:30-2:30 p.m. ET, Defining and Implementing Your HRPP Vision—The Importance of HRPP Leadership;** presenters include AAHRPP's Robert Hood, PhD.
- **November 18, 1:30-2:30 p.m. ET, Best Practices for Ancillary Review in a Single IRB World;** presenters include AAHRPP's Nichelle Cobb, PhD.
- **November 19, 11:30 a.m.-12:30 p.m. ET, A Philosopher's Look at the Belmont Principles (aka "Chicken Soup for the HRPP Professional's Soul");** presenters include AAHRPP's Robert Hood, PhD.
- **November 19, 3:00-4:00 p.m. ET, Protecting Research Participants During Emergencies: An Introduction to AAHRPP's Element I.1.H,** featuring Nichelle Cobb, PhD, and Robert Hood, PhD.