From the President and CEO

With signs that the pandemic is easing, President and CEO Elyse I. Summers, JD, looks to the future with guarded optimism, gratitude for our collegial community, and pride in AAHRPP’s accomplishments. LEARN MORE

Survey Results Highlight Value, Impact of Accreditation

Our 2021 survey results are in and indicate that AAHRPP accreditation is associated with quality, stronger protections for research participants, and increased emphasis on identifying opportunities for improvement. LEARN MORE

Introducing Our First CAN Working Groups

AAHRPP is tapping the expertise of our accredited organizations and relaunching our Collaborative AAHRPP Network (CAN) to address priorities identified in our recent survey of accredited HRPPs. LEARN MORE

A Q&A with AAHRPP’s Chair and Vice Chair

AAHRPP Board Chair Stephen Rosenfeld, MD, and Vice Chair Heather Pierce, JD, MPH, discuss the challenges facing AAHRPP and the research community—and the rewards of serving and guiding the global HRPP accreditation leader. LEARN MORE

How to Meet AAHRPP’s Standard I-9 for Single IRB Review

Single IRB review and AAHRPP’s related Standard I-9 continue to present challenges for some HRPPs. To help, AAHRPP outlines the top five things you should know about the standard. We also provide detailed instructions in our Evaluation Instrument for Accreditation and tip sheet on Single IRB or EC Review. LEARN MORE

NEWS & NOTES

Latest Accreditation: Albuquerque Clinical Trials Inc., Albuquerque, New Mexico

Upcoming Webinars:
• Summer 2022: Successful Tools for Educating and Evaluating HRPP Teams
• Fall 2022: Innovative Practices by AAHRPP-Accredited Organizations

Register today for the 2022 AAHRPP Annual Conference, May 24-26. With our hybrid format, you can attend in person in Denver or virtually.
From the President and CEO

**With Guarded Optimism, Gratitude, and Pride in Our Accomplishments**

Spring is just around the corner, and this year it feels particularly welcome. After a long, dark winter, promising signs are prompting many of us to move forward with guarded optimism.

Our 2022 AAHRPP Annual Conference is an excellent example. Following a pandemic-forced cancellation in 2020 and a virtual conference in 2021, this year we’ve come up with a hybrid solution. Our hope is to reunite with as many of you as possible in Denver in person. To accommodate those who cannot attend, we’re also offering a virtual option.

While we are cautiously optimistic about the prospect of bringing people together, we are unabashedly enthusiastic about the content we’ll be providing and the participation of all the teachers and learners who will be meeting in whatever medium. Regardless of how you participate, you will still benefit from informative, thought-provoking presentations from experts in our field.

The theme for the conference, “Community Commitment and Connection in Colorado,” is especially fitting. It speaks to our commitment and connection to each other and to the broader community we all serve. That commitment and connection have been more important than ever during the pandemic. They have fueled our resilience, our gratitude for one another, and our determination to move forward.

Certainly, the past two years have been wearying. We want the health of the world to improve, both medically and in terms of greater justice for all—and the pace of that change can sometimes be disheartening. On the other hand, there are glimmers of light, and we’re fortunate that we witness that light every day in the research community. Our incredible cadre of professionals and volunteers is the change we want to see personified.

Buoyed by your energy and support, AAHRPP is as productive as we’ve ever been. We are about to launch a new website and an online accreditation management system that reflect your input. As you will read in this newsletter, we recently completed our most comprehensive survey ever of HRPP administrators. We also are tapping the talent of our Collaborative AAHRPP Network to establish working groups on three topics of great interest to our accredited organizations: reaccreditation, DEI (diversity, equity, inclusion), and single IRB review. The first group has already begun meeting.

Of course, we continue to serve as a resource for accredited and not-yet-accredited organizations and to advance our goal of establishing one standard for research protections worldwide.

We remain focused on making things better—and, with your help, we’re succeeding. For that, as always, we are most grateful.

I look forward to your participation, in whatever form it takes, at our conference May 24-26.

Elyse I. Summers, JD
AAHRPP President and CEO
Accredited organizations overwhelmingly view AAHRPP accreditation as an affirmation of the quality of their human research protection program (HRPP). Perhaps even more important, these organizations associate accreditation with stronger protections for research participants and increased emphasis on identifying opportunities for improvement.

Those are just some of the findings of AAHRPP’s recent—and most comprehensive—survey of HRPP administrators.

Conducted by a survey center of an academic institution, the survey was distributed last summer to all accredited organizations. These include academic institutions, hospitals and health systems, independent IRBs, research institutes, and government entities around the globe. To protect confidentiality, AAHRPP did not receive any identifiable information related to survey responses.

AAHRPP will use the results to target areas for improvement and identify initiatives to better serve the HRPP community.

“Our goal was to get a frank assessment from our accredited organizations on the value of accreditation, what AAHRPP does best, and what we can do better,” says Nichelle Cobb, PhD, AAHRPP Senior Advisor for Strategic Initiatives. “We see the survey as an essential component of our commitment to continuous quality improvement—the same commitment we expect of our accredited partners.”

Survey questions touched on reasons for seeking accreditation, the impact of accreditation on the HRPP community, and the value of the accreditation process. The survey also sought input on virtual versus in-person site visits and which, if any, additional services and resources organizations would like AAHRPP to offer.

In addition, the survey asked whether organizations would be interested in participating in working groups focused on topics that pose challenges for organizations related to accreditation and beyond. In response, AAHRPP received the names of more than 100 volunteers—and has already launched the first of up to three working groups that will be introduced this year as part of the Collaborative AAHRPP Network (CAN) initiative.

**Survey highlights**

- More than 90% of survey respondents named each of the following reasons for pursuing accreditation:
  - Demonstrate the excellence of their HRPP.
  - Improve the protection of research participants.
  - Identify areas of improvement for the HRPP.
- 82.5% responded that accreditation encouraged periodic assessment of compliance, efficiency, and effectiveness of the HRPP.
- 77.8% responded that accreditation helped improve HRPP policies and procedures.
- 75% consider site visits to be “very” or “extremely” valuable.
- 71% view the accreditation process as “very” or “extremely” valuable.

In the comments section, HRPP administrators expressed support for changing the reaccreditation process for long-time accredited organizations. Partly because of that input, the first CAN working group—launched in February—is focusing on ways to maintain high standards while reducing the burden of earning reaccreditation.

“I am grateful to our organizations for taking the time to provide such thoughtful and helpful feedback to AAHRPP. The survey was the first step. Now we’re putting the information we’ve gathered to good use,” Dr. Cobb says.
INTRODUCING OUR FIRST CAN WORKING GROUPS

AAHRPP is tapping the expertise of our accredited organizations and relaunching our Collaborative AAHRPP Network (CAN) to address priorities identified in our recent survey of accredited human research protection programs (HRPPs).

The 2021 survey included an invitation to serve with AAHRPP staff on working groups that will tackle a variety of issues under the auspices of our CAN initiative. More than 100 respondents volunteered.

Modeled after the National Comprehensive Cancer Network (NCCN) IRB Directors Group, the CAN was created in May 2019 to foster collaboration among accredited organizations and provide a forum to problem-solve issues that affect IRBs. The first CAN meeting was well-attended, but momentum was stalled by the pandemic. The survey and follow-up working groups provide the ideal opportunity to resurrect the initiative.

Per the survey results, the first three issues that will be tackled are:

- Reaccreditation process
- Incorporating diversity, equity, and inclusion (DEI) in AAHRPP’s standards
- Single IRB review

Members of each working group will represent a range of organization types and sizes. The first group, on the reaccreditation process, held its initial meeting in February. Co-chairs are Candice Yekel, Associate Vice President for Research at Penn State University, and Robert Hood, PhD, AAHRPP Director of Accreditation and Global Outreach.

At least one more working group will be convened later this year; others will follow.

2022 AAHRPP Annual Conference

Mark your calendars for one of the research community’s must-attend annual events. This year’s conference is a hybrid learning experience, so you can join us in person in Denver or online.

Either way, you’ll hear thought-provoking presentations from experts in the field.

Register today.
In the following Q&A, Dr. Rosenfeld and Ms. Pierce discuss the challenges facing AAHRPP and the research community—and the rewards of serving and guiding the global HRPP accreditation leader.

Q. What drew you to the AAHRPP board and this new leadership role?

AAHRPP’s commitment to quality, ethical research and protecting participants was a key factor in both board members’ decisions to join the board and take on expanded roles.

A. S. Rosenfeld: There’s genuine value in working with people you respect to further something you believe in—in this case the mission of AAHRPP and making sure accreditation speaks to the needs of the people IRBs and HRPPs are supposed to protect. I feel that’s a really good use of my time, and I’m looking forward to serving as chair.

A. H. Pierce: Serving on the board and playing a leadership role provide a terrific opportunity to help guide AAHRPP’s growth and direction. I have spent the past 11 years at AAMC, one of the founding organizations of AAHRPP. Serving on the board is particularly meaningful for me and enables me to be part of AAHRPP in a different kind of way.

Q. What challenges are the board and AAHRPP facing?

Dr. Rosenfeld and Ms. Pierce agree that, like much of the rest of the world, AAHRPP’s task is to continue to move forward, building on the lessons of the pandemic.

A. S. Rosenfeld: The hard work of the pandemic—the pivoting to remote site visits and new ways to maintain relationships with accredited organizations—has been done by Elyse (Elyse I. Summers, JD, AAHRPP President and CEO) and Barbara (Barbara Entwisle, PhD, previous board Chair). What remains is to look at what we’ve learned and use that information to decide where to make changes. What we realized was that we were doing some things out of habit. There were options available to us, such as videoconference platforms, that no one had reason to take advantage of before. Now that we’re comfortable with them, one consideration is how best to deploy that technology—how to strike a balance between cost savings and maintaining the quality of the interpersonal exchange.

On the international front, there are so many challenges, and they are constantly changing! I am confident, though, that AAHRPP is up to the task.

A. H. Pierce: Most of AAHRPP’s challenges reflect those faced by HRPPs and are the

(continues on page 6)
result, in large part, of the pandemic, from budget constraints to meaningful changes in the way we were accustomed to conducting research prior to COVID-19. During the pandemic, we saw emergency revisions to regulations and modifications to some clinical trial procedures. At the same time, we learned a lot about how connecting with research participants remotely can be not only efficient from a research perspective but can improve the participant experience as well.

Now, as we move beyond the pandemic, we’re seeing reductions both in restrictions and in flexibility. Part of our challenge will be to help the research community adapt to evolving circumstances, including potential changes in federal requirements about the way people participate in research.

Q. Looking ahead, what can the research community expect from AAHRPP?

A. S. Rosenfeld: AAHRPP is in the process of moving to an online accreditation management system that, in the very near future, will dramatically reduce the burden of applying for accreditation or reaccreditation. As a past CIO (chief information officer), I am confident this will be a welcome change. On other fronts, much of what we focus on will be an extension of what we’ve always done. AAHRPP will remain a strong voice on behalf of research participants and a resource for organizations seeking to maintain high standards for safe, ethical research.

A. H. Pierce: AAHRPP will continue to grow, help the research community respond to an ever-changing landscape, and create an atmosphere that supports and sustains best practices. Ours is a very collegial, collaborative community, and AAHRPP helps drive and nurture that. I expect AAHRPP to keep building on successful efforts to bring people together to exchange policies and documents, share approaches that seem to be working, and develop innovative solutions.

It’s been wonderful to see AAHRPP reach beyond U.S. borders and engage so many people in the research community. I look forward to even more of that in the future.

Helpful Hints on Meeting AAHRPP’s Standard for Single IRB Review

Two years after their effective date, Common Rule requirements for cooperative research continue to pose challenges for organizations that previously had little or no experience with single IRB review. Many are still familiarizing themselves with the roles of reviewing and relying organizations—and the importance of developing plans to address these responsibilities.

AAHRPP’s Standard I-9 and the related Tip Sheet: Single IRB or EC Review can help.

Standard I-9, which aligns with the Common Rule, is presented in detail in the Evaluation Instrument for Accreditation. The tip sheet provides a step-by-step guide to meeting the standard’s requirements. Both the Evaluation Instrument language and tip sheet are the result of working group and other collaborative efforts launched by AAHRPP in 2016 after the Common Rule revisions were announced.

“Independent IRBs and other institutions were already in this arena, but what we heard loud and clear from organizations that had never done this before was ‘Help,’” says Robert Hood, PhD, AAHRPP Director of Accreditation and Global Outreach.

“Through a peer-driven process involving organizations experienced in single IRB review, we developed a standard and tip sheet to guide organizations on working collaboratively to protect participants when you’re sharing research.”

(cont. on page 7)
TOP 5 THINGS YOU SHOULD KNOW ABOUT STANDARD I-9

1. Reliance arrangements must be documented (e.g., a memorandum of understanding, attestation, or reliance agreement) and must identify the roles and responsibilities of the reviewing IRB and relying organization.

   • An example of an agreement that meets Standard I-9 is the SMART IRB Agreement (https://smart-irb.org/assets/files/SOAR_IRB_Agreement_Sample_Agreement.pdf).
   • Reliance arrangements for Department of Health and Human Services (DHHS)-funded research should address additional requirements, such as which organization is responsible for:
     o Obtaining any additional approvals from DHHS when the research involves pregnant women, fetuses, and neonates; or children; or prisoners.
     o Reporting serious or continuing noncompliance, unanticipated problems involving risks to participants or others, and suspensions or terminations of IRB or EC approval.

2. Local requirements and local research context information must be communicated.

   • Reviewing IRBs need to collect, and relying organizations need to identify and provide, local context information relevant to the IRB’s determinations prior to IRB review.
   • Local context includes information about the relying organization (e.g., state and local laws, FWA status) and study implementation (e.g., conflict of interest management plans related to the research, permitted recruitment methods, training and qualifications of research personnel).

3. Organizations should identify relevant contact people for reliance arrangements.

   • Reviewing IRBs need to identify a contact person for researchers and research staff to obtain answers to questions, express concerns, and convey suggestions regarding the IRB.
   • Relying organizations should specify the person researchers and research staff can contact to obtain answers to questions, express concerns, and convey suggestions regarding using the reviewing IRB.

4. If your organization serves as a reviewing IRB, it needs to:

   • Make relevant IRB policies readily available to relying organizations, including HRPP staff, and researchers and research staff.
   • Identify in your organization’s policies or procedures how your organization will conduct review of the addition of sites to previously approved studies. The tip sheet provides examples of how organizations can approach this.

5. When your organization relies on another organization’s IRB, your organization needs to:

   • Specify which studies are eligible for review by another organization’s IRB and describe the mechanism for making the determination.
   • Retain responsibility for ensuring research team compliance with reviewing IRB determinations and applicable regulations, laws, and policies.
   • Educate researchers about which activities are eligible for review by another IRB and the need to obtain any approvals from their own organization prior to seeking review by another IRB.

The 2022 AAHRPP Annual Conference will feature two breakout sessions on Standard I-9 and single IRB review:

   • Single IRB: Understanding and Applying AAHRPP’s Standard I-9
   • Challenges and Solutions for sIRB: The Struggle Is Real