

AAHRPP ADVANCE

One Standard Worldwide

FALL 2020

From the President and CEO

AAHRPP President and CEO Elyse I. Summers, JD, discusses AAHRPP's response, as a global leader in research protections, to the challenges of two pandemics: COVID-19 and systemic racism. [LEARN MORE](#)

Site Visits Go Virtual

We have transitioned to remote site visits to ensure the important work of accreditation and reaccreditation continues without interruption during the pandemic. Although the format has changed, the quality and rigor of the review remain the same.

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Tackling Issues of Diversity, Inclusion, Equity, and Justice

AAHRPP joins individuals and organizations within and beyond the research community in denouncing systemic racism and affirming and acting on a commitment to diversity, inclusion, equity, and justice. [LEARN MORE](#)

Free Educational Videos on YouTube

Organizations interested in pursuing accreditation and reaccreditation now have access to free educational information previously available only to attendees of AAHRPP's pre-conference workshops. The eight-video series is posted on [YouTube](#). [LEARN MORE](#)

Save the Date

Please save the date for the 2021 AAHRPP Conference, which is scheduled for May 18-21. Most likely this will be a virtual event. Please plan on joining us.

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LATEST ACCREDITATIONS

- **Principal IRB, Inc.**, Deland, Florida
- **Western Michigan University Homer Stryker, MD, School of Medicine**, Kalamazoo, Michigan

OF NOTE

Congratulations to AAHRPP Site Visitor Linda Mayo, CIP. The director of the Office of the IRB for The University of New Mexico, Ms. Mayo recently was honored with the Applied Research Ethics National Association (ARENA) Legacy Award from PRIM&R. The award recognizes individuals for contributing to a more ethical research enterprise through professional leadership, education, and mentoring.

From the President and CEO

Taking On Two Pandemics

Like the times we live in, this issue of *AAHRPP Advance* is unusual. Most of it focuses on our response to two deadly pandemics: COVID-19 and systemic racism.

As a global leader in research protections, AAHRPP has a responsibility to take on both. With COVID-19, our challenge is to make sure the pandemic does not disrupt the accreditations and reaccreditations that play an essential role in protecting research participants. AAHRPP has been engaged in this important work for nearly 20 years, and it will take more than a pandemic to stop us.

For the foreseeable future, all **site visits** are being conducted remotely. Early feedback from research organizations and site visitors has been positive. Both groups agree that, while they miss the in-person interaction, the quality and rigor of the site visits haven't changed. As always, please don't hesitate to ask questions if you have a site visit coming up—or to provide input on what we can do better.

To help organizations prepare for accreditation or reaccreditation during the pandemic, we're offering free educational **videos** that cover information previously available only as part of our annual conference. We extend our heartfelt appreciation to the individuals who made this possible by presenting their conference sessions.

Confronting systemic racism

The other pandemic, systemic racism, has been with us far longer. As we all know, the field of research protections and the principles of the Belmont Report were established because certain groups of research participants were viewed as “other” and, therefore, not deserving of equitable treatment.

For centuries, our nation did its best to ignore or dismiss systemic racism. That changed in May with the release of videos of the killing of George Floyd. We could no longer ignore this pandemic. We could no longer be silent.

Many in the research community, including AAHRPP, issued statements condemning racism and affirming our commitment **to diversity, inclusion, equity, and justice**. AAHRPP asked board



ELYSE I. SUMMERS, JD

member Dr. Quincy Byrdsong, a frequent presenter on these topics, to conduct an all-staff meeting for the AAHRPP team. We continued the discussion in a second session, presented by AAHRPP Executive Assistant Danielle Randolph.

These were difficult, sometimes uncomfortable, conversations, but they helped break down barriers we weren't even aware of. We will continue these discussions. Even more important, we will do our part to turn words into action and achieve measurable results. And we are not alone.

We are privileged to be part of a community that contributes to the advancement of humanity. Our community and our shared values give us hope and cause for optimism during times like these.

Looking ahead to next spring, we have scheduled the 2021 AAHRPP Annual Conference for May 18-21. While it's increasingly likely that this will be a remote event, we will endeavor, as always, to bring the leading lights in research ethics and education to you. So please save the date. It will be so wonderful to “see” you.

Best,

A handwritten signature in blue ink that reads "Elyse I. Summers". The signature is fluid and cursive.

Elyse I. Summers, JD
AAHRPP President and CEO

Site Visits Go Virtual

AAHRPP has transitioned to remote site visits to ensure that the work of accreditation and reaccreditation continues without interruption during the pandemic. All site visits will be conducted remotely for the foreseeable future.



KATE VULAKOVICH

The change is driven, in part, by AAHRPP's recognition that organizations have devoted significant time and resources to preparing for accreditation. "To delay their site visits seemed almost unfair. It would be another disappointment in an already difficult time," says Kate Vulakovich, AAHRPP Director of Operations.

"At the same time, we realize that any change brings challenges," she adds. "To mitigate those, true to AAHRPP tradition we've designed a process that's flexible, and we've built in lots of support."

Perhaps most important, as John Horigan and Julie Ozier can attest, the remote visits retain the quality and rigor of the in-person assessments.

Mr. Horigan, MA, CIP, was the HRPP director at Virginia Commonwealth University (VCU) and team leader for its remote reaccreditation visit in early May. (He now serves as director of IRB and protocol compliance at the National Institutes of Health All of Us Research Program.) Ms. Ozier, MHL, CHRC, CIP, is the HRPP director for Vanderbilt University and Vanderbilt University Medical Center. An AAHRPP site visitor and Council on Accreditation member, she has conducted three remote site visits.

"During the remote visits, the site visitors have the same level of access to documents, and they interview the same individuals,"

Mr. Horigan says. "They have everything they need to conduct a comprehensive, high-quality review."

Ms. Ozier agrees. "You can be just as rigorous remotely," she says. "So much of the process is based on conversation, on back-and-forth questions and answers. That dialogue doesn't change, whether you have it in person or via Zoom, Webex, or whatever platform the applicant chooses."



JULIE OZIER

The similarities are intentional. A key goal, Ms. Vulakovich says, "is to maintain the infrastructure of the in-person visit and simulate it in the remote format. As much as possible, we want the remote visits to feel the same as in-person ones."

For this reason, the agenda for remote visits is based on the time zone of the organization seeking accreditation or reaccreditation. In the vast majority of cases, the schedule will be identical to that of an in-person visit.

Ms. Vulakovich, Mr. Horigan, and Ms. Ozier offer the following tips for a smooth, successful remote visit:

- **Make the most of the AAHRPP pre-meeting.** To help prevent technology glitches, AAHRPP requires organizations to schedule a test session at least three days before the remote visit. This is an opportunity to make sure the audio and video are clear, everyone can sign in, site visitors can access all necessary documents and know what to expect during the interview process. Mr. Horigan suggests taking it a step further and having your own in-house trial run ahead of time. "It will make your team more comfortable and, during the official pre-meeting, give you an opportunity to say, 'This is what we tried. Let's see how it works for all of us today,'" he says.

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Site Visits Go Virtual (cont. from page 3)

- **Tap IT resources within your organization.** If you have access to information technology staff through your organization, ask to have someone on standby just in case—during both the pre-meeting and the site visit. Knowing you have that safety net will reduce your team’s anxiety and free them to focus on other issues.
- **Be as organized as possible.** Just as with an in-person visit, preparation and organization make a difference. For a remote visit, consider how best to organize the documents that site visitors have requested. VCU created an electronic directory with links to each document to make it easy for site visitors to find exactly what they were looking for.
- **Take a team approach.** Choose several staff members to provide meeting support. For example, have someone serve as the host, another person run the video platform, and yet

another be ready to respond to site visitor requests for help or information.

- **Be prepared to adjust your communications style to accommodate the technology.** “When you’re not meeting face to face, it’s harder to pick up on subtle cues,” Ms. Ozier says. “To avoid confusion and misunderstanding, be clearer and more pointed in your communications.”

One final tip, from Ms. Vulakovich:

“Relax. It’s easy, especially during the pandemic, to get caught up and become anxious about what’s different. Focus on what hasn’t changed—that you can rely on AAHRPP staff to keep you moving in the right direction.”

FREQUENTLY ASKED QUESTIONS ABOUT REMOTE SITE VISITS

1. Who would set up the remote site visit? AAHRPP or the organization?

Each organization is responsible for setting up the logistics of the remote site visit. If the organization has questions or concerns, they should contact AAHRPP at sitevisits@aahrpp.org.

2. What activities should occur prior to the remote site visit?

The organization is required to participate in a pre-site visit check-in with the site visitors to ensure that there are no issues with the technology used for logging on to the remote site visit. Ideally, this meeting will occur, at a minimum, three days prior to the remote site visit. The organization will make arrangements for this check-in.

Congruent with this, the organization should make sure that the Documents to Pull that have been identified for the site visit are available at a time prior to the site visit that is no later than the technology check-in meeting referenced above. This will allow all parties to the site visit an opportunity to confirm the availability of the documents and to troubleshoot (and fix) in advance any IT issues related to the documents’ availability.

3. Who is in charge of setting up and monitoring each session during the remote meetings?

AAHRPP requests that organizations monitor each of the sessions to ensure they proceed as smoothly as possible and that individuals do not call in to the conference call until it is time for their session. Each organization is responsible for setting up the conference call line(s).

4. Can a staff member be present in the meeting to monitor?

A representative from the organization may not be present but should be readily available to the site visit team to assist in the event the site visit team has questions or needs assistance with the technology.

5. Does AAHRPP require an IT representative to be available during these sessions?

The organization should ensure that the remote site visit runs as smoothly as possible and is responsible for ensuring they have the expertise available for whatever IT is used during the site visit (i.e., options range from a traditional teleconference to the use of visual technologies such as Zoom or Webex).

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6. Do the organization's interviewees need to be present in the meeting room onsite or may everyone call in?

Under normal circumstances it would be preferable (though not required) for all interviewees for a particular session to be together in the meeting room; however, given the current coronavirus public health emergency, it is expected and acceptable for interviewees asked to work remotely to be in their individual remote work spaces.

7. Do the interviewees need access to video?

Video conferencing is helpful, but a telephone conference would be acceptable.

8. How will the calls be controlled or monitored for people entering or exiting the meeting?

The Team Leader will take roll call at the beginning of each session. Organizations will be asked to inform the interviewees not to call in to the conference call until it is time for their session.

9. Can my organization record the site visit?

No. AAHRPP does not allow the video or audio recording of a remote or in-person site visit in order to preserve the integrity of the open dialogue that must occur during the site visit between the individuals in your HRPP and the site visitors.

10. Do the site visitors need to travel to be together in one room?

No, in fact, generally the site visitors should participate in the remote site visit from their own individual geographical "home" location.

11. How will the agenda accommodate time zone changes?

The agenda will list sessions based on the time zone of the organization, and in the overwhelming majority of cases, be identical to that which would be used for an in-person site visit.

12. Is there any potential violation of confidentiality?

The same procedure for an onsite visit will be followed for attendance at each session during the remote site visit; only appropriate individuals will be in attendance. The Team Leader will enforce these restrictions, as usual.

13. How will site visitors access records?

All relevant records must be accessible electronically to the site visitors, either through access to the organization's database or to documents uploaded to a cloud server. Ideally, the organization will provide site visitors with access to their records prior to the site visit.

14. Will a secondary or follow-up in-person site visit be needed?

The remote site visit is designed to take the place of an in-person visit in toto. Therefore, the exceedingly rare circumstances for a follow-up visit would be the same as if the visit had been conducted in person, that is, if significant issues are identified or the site visit cannot be completed fully.

As with any site visit, the preferred outcome is that no secondary follow-up is necessary. Follow-up site visits are rare but occasionally occur if significant issues are identified or the site visit cannot be completed fully.

15. If an organization does not want to proceed with a remote site visit, will AAHRPP reschedule the site visit?

Due to the public health emergency, we understand that some organizations are directly involved in finding solutions and are unable to spare staff for a site visit. AAHRPP will be flexible and willing to postpone a site visit with no negative consequences, if such becomes necessary.

*These **FAQs** are also available on the AAHRPP website.*

Tackling Issues of Diversity, Inclusion, Equity, and Justice

It is AAHRPP's mission to defend and protect the safety and welfare of human beings ... to protect all people and promote human dignity and ethical behavior. ... We pledge that, in our words and in our deeds, AAHRPP will remain tireless in our dedication to uphold the time-tested principles of respect, beneficence, and justice, the values that will ultimately determine the fate of our future and soul of our nation.

From [AAHRPP Anti-Racism Statement: Black Lives Matter](#)

AAHRPP joins individuals and organizations within and beyond the research community in denouncing systemic racism and affirming and acting on a commitment to diversity, inclusion, equity, and justice.

These issues are timely but not new. AAHRPP was founded in part to help prevent research abuses—such as the Nazi medical experiments and Tuskegee and Guatemala syphilis studies—that were rooted in racist beliefs and injustice.



DR. QUINCY BYRDSONG

What *is* new, according to AAHRPP Board Member Quincy Byrdsong, Ed.D., CIP, CCRP, are the types of conversations that research organizations are starting to have.

“We really haven’t been talking about this at all,” he says. “We’ve been limiting our discussions to the need for more minority participation in research, when we should also be saying, ‘There are legitimate and historic reasons not to trust us.’”

Equally important, Dr. Byrdsong says, is the statement that should follow: “We understand that you’re protecting yourself from mistreatment and making sure your trust is not violated, but in doing so, you’re also removing your voice from the equation.”

The goal, he says, is not just to enroll more minorities in clinical trials but also “to give them a place at the table, an opportunity to contribute to science and reap its benefits.”

Dr. Byrdsong is president of the Society of Clinical Research Associates (SOCRA), vice provost for health affairs at Lipscomb

University, and a frequent presenter on diversity, inclusion, equity, and justice. At AAHRPP’s request, he conducted an all-staff meeting on equity and justice for the AAHRPP team in July. In August, AAHRPP followed up with a discussion on diversity and inclusion, led by AAHRPP Executive Assistant Danielle Randolph.



DANIELLE RANDOLPH

Both presenters emphasized the need to acknowledge and embrace diversity, which, by definition, focuses on the many ways that people are different.

“It’s a lot more comfortable to say, ‘We’re all human; we’re all the same,’” Ms. Randolph says. “But those differences are important, and unless we recognize them, we won’t understand how they affect the way we interact with one another.”

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EQUITY-RELATED ACCREDITATION STANDARDS & ELEMENTS

AAHRPP has always required accredited organizations to respect and engage communities and treat research participants fairly and equitably.

STANDARD I-4

- **Element I.4.B.** The Organization conducts activities designed to enhance understanding of human research by participants, prospective participants, or their communities, when appropriate. These activities are evaluated on a regular basis for improvement.
- **Element I.4.C.:** The Organization promotes the involvement of community members, when appropriate, in the design and implementation of research and the dissemination of results.

STANDARD II-3

- **Element II.3.C.** The IRB or EC has and follows written policies and procedures to evaluate the equitable selection of participants.

STANDARD III-1

- **Element III.1.E.** Researchers and research staff recruit participants in a fair and equitable manner.

Actions and Deliverables

Failure to acknowledge differences can affect key decisions in the research enterprise, including what to study and whom to include in research trials. If researchers overwhelmingly represent the same community, studies will tend to focus on that community's concerns.

HRPPs can help guard against this tendency by viewing study design, IRB and research team composition, and trial enrollment through the lens of diversity, inclusion, equity, and justice. The academic and scientific community can also help lay the foundation for a more diverse, inclusive research enterprise by encouraging students of all races, ethnic groups, genders, sexual identities, and socioeconomic groups to pursue research-related careers.

Conversations about systemic racism, diversity, inclusion, equity, and justice must continue and must include “deliverables that we can measure,” Dr. Byrdsong says. “It’s time to talk about what success in these spaces looks like.”

Free AAHRPP Educational Videos

Organizations interested in pursuing accreditation or reaccreditation now have access to free educational information previously available only to attendees of AAHRPP’s pre-conference workshops.

The eight-video series is posted on [YouTube](#) and includes the following:

- **[What to Expect When We’re Accrediting](#)**
Monika Markowitz, PhD, Virginia Commonwealth University
Julie Ozier, MHL, CHRC, CIP, Vanderbilt University and Vanderbilt University Medical Center
- **[How to Conduct the Self-Assessment](#)**
Amal Al Omari, MS, PhD, King Hussein Cancer Center
Rhonda Oilepo, MS, CIP, CHRC, University of Texas Southwestern Medical Center
- **[Responding to the Step 1 Review](#)**
Kristin Craun, MPH, CIP, UCLA
K. Sue Haddock, PhD, Dorn Research Institute
- **[Site Visit Dos and Don’ts – An Organizational Perspective](#)**
Sana Khoury-Shakour, PhD, University of Michigan
Joshua Fedewa, MS, CIP, University of Texas Southwestern Medical Center

He is optimistic that such discussions will occur and spur progress, in part because they have widespread support throughout the research enterprise. Like AAHRPP, many in the research community have made public statements condemning systemic racism and declaring their commitment to diversity, inclusion, equity, and justice. Examples—and there are many more—include the [Association of American Medical Colleges](#) (AAMC), [Public Responsibility in Medicine and Research](#) (PRIM&R), [National Institutes of Health \(NIH\) Director Francis S. Collins, MD, PhD](#), and [Association of Clinical Research Professionals](#) (ACRP).

“Professional organizations related to research are in solidarity on this. We agree that we can’t be silent,” Dr. Byrdsong says. “We will keep having these conversations, until we get concrete deliverables.”



(cont. on page 8)

Free AAHRPP Educational Videos (cont. from page 7)

- **Site Visit Dos and Don'ts – A Site Visitor Perspective**
Nichelle Cobb, PhD, University of Wisconsin-Madison
Delia Wolf Christiani, MD, JD, MSCI, Harvard T.H. Chan School of Public Health
- **Responding to the Site Visitor Report: A Wrap-up from AAHRPP**
Wesley Byerly, PharmD, CIP, University of Connecticut Health Center
Kate Vulakovich, BS, CCRP, AAHRPP
- **Responding to the Concerns of Participants and the Community: Understanding Standard I-4**
Courtney Jarboe, MS, CIP, University of Minnesota
Robert Hood, PhD, AAHRPP
- **Exploring COIs and Contracts: Standards I-6 and I-8**
Heather Pierce, JD, MPH, Association of American Medical Colleges
J. Andrew Bertolatus, MD, University of Iowa

The videos provide the same information attendees would have received during the pre-conference presentations, which, as part of the 2020 AAHRPP Conference, were canceled due to the COVID-19 pandemic.

AAHRPP is offering the educational videos at no charge to help research organizations during a difficult time. “Organizations face many challenges responding to COVID-19,” says **Robert Hood**, PhD, AAHRPP Director of Accreditation. “This is one way we can provide additional support and encouragement.

“Of course, it wouldn't be possible without those who shared their presentations,” he adds. “These are people who are extremely busy and still happy to help. We are fortunate and grateful to be part of such a generous community.”



2021 AAHRPP ANNUAL CONFERENCE
MAY 18-20, 2021

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