

# AAHRPP ADVANCE

One Standard Worldwide

SUMMER 2021

## From the President and CEO

President and CEO Elyse I. Summers, JD, marks AAHRPP's 20th anniversary by emphasizing the collaboration at the heart of AAHRPP's accomplishments—and the resulting shared, laudable legacy. "AAHRPP's achievements are your achievements." [LEARN MORE](#)

## 2021 Conference: A 'Virtual' Success

More than 500 attendees from around the globe logged in for the 2021 AAHRPP Annual Conference: Real Research In A Virtual World. *AAHRPP Advance* provides plenary session highlights plus, for conference registrants, a link to on-demand content. [LEARN MORE](#)

## Q&A with Nichelle Cobb, Senior Advisor for Strategic Initiatives

Nichelle Cobb, PhD, recently joined AAHRPP as senior advisor for strategic initiatives. In this Q&A, she shares some thoughts on her new role and how AAHRPP can continue to best serve an ever-changing research community. [LEARN MORE](#)

## 20 Years of Accreditation and Accomplishments

On AAHRPP's 20th anniversary, *Advance* notes ways that AAHRPP and AAHRPP-accredited organizations have helped transform the research enterprise. We also showcase quotes from AAHRPP leaders and give a much-deserved shout-out to our founding members. [LEARN MORE](#)

## Upcoming Webinar

Join us July 27, from 1:00-2:30 p.m. ET, for Protecting Research Participants During Emergencies, a webinar on AAHRPP's New Element I.I.H. [Registration](#) is free for AAHRPP client organizations.

SUMMER 2021

## INSIDE

2 From the President & CEO

3 Conference Highlights

6 Senior Advisor for Strategic Initiatives

7 Happy Anniversary, AAHRPP!

### LATEST ACCREDITATIONS

- **Albert Einstein College of Medicine and Montefiore Medical Center**, Bronx, N.Y.

### CONGRATULATIONS

- To **Judy Birk, JD**, Director, Institutional Review Boards, University of Michigan, honored with the AAHRPP Distinguished Site Visitor Award.
- To **Julie Ozier, MHL, CHRC, CIP**, Director, Human Research Protection Program, Vanderbilt University, honored with the AAHRPP Team Leader Award.
- To **Charlotte Coley, MACT, CIP**, Training Coordinator, Office of Human Research Ethics, University of North Carolina, Chapel Hill, honored with the AAHRPP Lifetime Achievement Award.

## From the President and CEO

### *We're All Part of AAHRPP's History—and Its Future.*

This is a milestone year for AAHRPP: our 20th anniversary as your partner in the noble endeavor of protecting research participants.

In the midst of our busy schedules, few of us pause to look back at where we've been and how far we've come. I urge you to take a moment to do just that—to consider how much we've all accomplished these past two decades and to give yourselves the credit you deserve. AAHRPP's achievements are your achievements, and we highlight some of them on [page 7](#).

AAHRPP has always been a collaborative effort. Long before our founding, members of the research enterprise were grappling with the need to improve research oversight and protections for participants. Rather than rely on government regulation, research leaders drew on the strengths of our own community. The resulting solution—a nonprofit organization that would rely on a voluntary, collegial, educational accreditation process—was made possible by a partnership of seven founding members. Through their efforts, AAHRPP was incorporated in April 2001 and has been advancing high-quality, ethical research ever since.

Ours is a proud history, and you have played an instrumental role. Equally important is what comes next. Together, we will shape AAHRPP's future and continue to make meaningful contributions to the quality of research and the well-being of research participants.

That's a laudable legacy for all of us.

Our community is extraordinary for its resilience, collaboration, and innovation, and those traits were on display once again during our recent AAHRPP conference. Like so many gatherings of the past year, the conference was a virtual event. Yet, despite “Zoom fatigue” attendees tuned in from around the globe and gave our presenters rave reviews.

This year's plenary sessions covered three topics that few would have anticipated 20 years ago: human gene editing, data and privacy, and ethics of emergency use authorizations (EUs). Our opening session focused on health inequity and social justice, an issue that has been with us far too long.



ELYSE I. SUMMERS, JD

All four plenary sessions were informative, insightful, and thought-provoking. We provide highlights starting on [page 3](#). If you registered for the conference, you also have access to those sessions [on demand](#). To the conference presenters, our sponsors and exhibitors, poster presenters, and my wonderful AAHRPP team, thank you for making the 2021 event a “virtual” success.

Thanks, too, to all of you who have worked tirelessly and heroically during the pandemic. It is truly a privilege to be part of this community.

Finally, to all supporters of AAHRPP and AAHRPP accreditation, know that you have our utmost appreciation for your enduring commitment to safeguarding participants, promoting ethical research, and making discovery possible.

Here's to the next 20 years and beyond!

Best,

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

# 2021 AAHRPP CONFERENCE: A 'VIRTUAL' SUCCESS

More than 500 attendees from around the globe logged in May 18-20 for the 2021 AAHRPP Annual Conference: Real Research In A Virtual World.

Although it was presented remotely, the conference incorporated nearly all the features attendees have come to expect:

- A pre-conference day for organizations pursuing AAHRPP accreditation or reaccreditation.
- Thought-provoking and educational plenary and breakout sessions.

- “Friends of AAHRPP” awards and recognition of newly accredited organizations.
- Poster presentations.
- Sponsor and exhibitor “booths.”

The virtual format proved popular with attendees, who welcomed the flexibility to participate in real time or at their convenience. Sessions remain available to registrants **on demand** for 12 months.

Following are highlights from the four plenary sessions.

## Health Inequity and Social Justice in the Time of COVID

(On-demand video and slides available)

### Presenters:

#### **ROBIN STEINBERG, JD**

CEO, The Bail Project

#### **QUINCY BYRDSONG, EdD**

Vice Provost for Health Affairs, Lipscomb University

AAHRPP Board Member

SOCRA President

Ms. Steinberg focused on the failed experiment of the U.S. cash bail and incarceration system. Nearly every hypothesis—including that cash bail would make people return to court, incarceration would solve social problems, targeting minorities would reduce crime, and militarizing police would be effective—has been proved false. Instead:

- Inability to pay bail is the leading driver of incarceration in America, with pretrial detention due to unaffordable bail accounting for nearly 100% of jail growth over the past 25 years.
- Nearly 500,000 people go to bed in U.S. jail cells each night without having been convicted of anything, and about 2.5 million are held each year because they can't afford bail.
- Black and Latinx people are significantly over-represented, accounting for more than 50% of the pretrial jail population.

- Innocent people who can't afford bail often plead guilty because it's the only way to get home to safety and family, a decision that negatively affects the rest of their lives.

Dr. Byrdsong followed with an overview of health inequity and social injustice in the U.S., from the time of slavery through COVID-19's disproportionate toll on Black and Hispanic populations. His “Byrdsong Report: Ethical Principles for Health Equity and Social Justice” offered a blueprint to incorporate equity and justice in human research protections by emphasizing:

- Information – Taking the time, even if it requires lengthy discussions, to provide the information that enhances decision-making and facilitates trust.
- Independence – Acknowledging the research participants' autonomy and respecting their decision.
- Importance – Treating every individual with concern, compassion, and empathy.

### **Two key points:**

- Ethical research is not just about how we conduct a study but how we treat people.
- The good of science can never be considered over the importance of human life.

## Ethics of Emergency Use Authorizations

(On-demand video and slides available)

### Presenters:

#### HOLLY FERNANDEZ LYNCH, JD, MBE

John Russell Dickson, MD, Presidential Assistant Professor of Medical Ethics, Perelman School of Medicine, University of Pennsylvania

#### ROBERT W. FRENCK, JR., MD

Professor of Pediatrics, Division of Infectious Diseases Cincinnati Children's Hospital Medical Center (CCHMC) Director, Center for Vaccine Research at CCHMC

#### DAVID WENDLER, PhD

Head, Section on Research Ethics NIH Clinical Center

Before COVID-19, few were familiar with emergency use authorization (EUA), a regulatory pathway established in 2004 as part of the U.S. response to concerns about bioterrorism. The EUA program allows FDA

to authorize the use of unapproved medical products as well as unapproved uses of existing products during a "declared emergency." The Department of Health and Human Services made that declaration for COVID-19 on March 27, 2020. Since then, FDA has issued hundreds of EUAs for therapeutic products, devices and, most notably, vaccines.

Takeaways from this presentation include:

- Access over evidence: Because of "emergency exceptionalism," EUAs prioritize "We have to do something" vs. "We have to learn what to do."
- Potential downsides of EUAs: Once investigational products are widely available, it can be difficult to gather critical evidence or rally support for exploring other options.
- Reasons to continue a vaccine clinical trial after an EUA:
  - Learn more about the length of protection.
  - Identify correlates of immunity.
  - Evaluate protection against variant strains.

## The Ethical, Regulatory, and Research Complexities of Human Gene Editing

(On-demand video and slides available)

### Presenters:

#### STEPHEN ROSENFELD, MD

President, Freeport Research Systems AAHRPP Board Member

#### JEFFREY KAHN, PhD

Andreas C. Dracopoulos Director Johns Hopkins Berman Institute of Bioethics

CRISPR and other gene-editing technologies offer enormous promise for treating, and even curing, genetic diseases. The technology also raises the prospect of heritable human genome (HHGE) editing and the resulting ethical dilemmas.

In their description of this session, Drs. Rosenfeld and Kahn cautioned attendees not to expect answers. Instead, presenters

highlighted challenges created by a game-changing technology in a decentralized global research arena. In Dr. Rosenfeld's words, "The larger ethical decisions are profound but do not belong to the research ethics community."

Dr. Kahn, a member of an international commission on the clinical use of HHGE, raised governance issues, including:

- Decisions on approving HHGE will ultimately be made by countries.
- Societal and cultural differences could lead to significant differences in governance informed by the same set of principles.
- Principles and recommendations are not the same as governance.
- Translating into governance requires privileging some principles over others.

# 2021 AAHRPP CONFERENCE: A 'VIRTUAL' SUCCESS

## Data and Privacy in 2021: Consent? Really?

(On-demand video available)

### Presenters:

#### DAVID MEDINE, JD

Consultant, Medine Consulting  
Expert in privacy and data security

#### HEATHER PIERCE, JD, MPH

Senior Director for Science Policy,  
Regulatory Counsel, AAMC;  
AAHRPP Board Member

Billed as AAHRPP's "great debate," this session featured Mr. Medine and Ms. Pierce facing off on four consent-related assertions.

- Assertion 1: Consent is dead. Defender, Mr. Medine; rebuttal, Ms. Pierce.
- Assertion 2: Research with human subjects is different. Defender, Ms. Pierce; rebuttal, Mr. Medine.
- Assertion 3: Disclosures create noise, not comprehension. Defender, Mr. Medine; rebuttal, Ms. Pierce.
- Assertion 4: Consent is key. But we can do better. Defender, Ms. Pierce; concurrence, Mr. Medine.

If you registered for the conference, you can view all four plenary sessions and download accompanying presentations. Simply [log in](#) to receive a verification code and obtain access.

# 2022 AAHRPP Annual Conference



**Save the Date for the 2022 AAHRPP Conference**  
**IN PERSON May 24-26**  
**at the Grand Hyatt Denver, Colorado**

**Looking forward to being together again!**

## Nichelle Cobb Joins AAHRPP As Senior Advisor for Strategic Initiatives

Nichelle Cobb, PhD, has joined AAHRPP in the new role of senior advisor for strategic initiatives. She continues to serve as senior advisor for SMART IRB.

Dr. Cobb has more than two decades of experience working with IRBs, including as director of the health sciences IRBs at the University of Wisconsin-Madison (UW-Madison) and as the human subjects protections officer for the Institute for Clinical & Translational Research at UW-Madison. In the following Q&A, the longtime supporter of AAHRPP and accreditation shares some thoughts on her new role and how AAHRPP can continue to best serve an ever-changing research community.



**NICHELLE COBB, PhD**

### Q. What strategic initiatives will you focus on?

**A.** A lot depends on our AAHRPP-accredited colleagues and their needs. One of the first things we'll do is survey our accredited organizations on additional ways AAHRPP can support them. We want AAHRPP to continue to be a "go-to" resource for organizations as they face the challenges of an evolving research enterprise. Our goal is to give organizations both the space and assistance to help them sustain and improve their high-quality HRPPs.

We also want to enhance our role as a convener—to bring people together to brainstorm and share innovative approaches. One way is to build on the success of The Collaborative AAHRPP Network (CAN), which was launched as a pilot program in 2019. Already, the CAN is providing opportunities for accredited organizations to ask each other, "What made you decide to do it that way?" and, equally important, "How is that working?" Once you have those conversations, you begin to see that instead of recreating your own wheel, you can build a new, better one.

We expect to provide similar opportunities for our site visit team leaders by meeting more regularly, seeking their feedback, and discussing ways we can enhance the accreditation experience.

### Q. Why is AAHRPP adding this role now?

**A.** This is both a natural progression for AAHRPP and a reflection of leadership's determination to maximize AAHRPP's positive impact on the research enterprise. We have a critical mass of accredited organizations that can collaborate to lift up the entire research community. Whether we're talking about equity and inclusion, informed consent, gene editing, or numerous other issues, AAHRPP and our accredited organizations can add enormous value and ensure that protecting research participants remains center stage. I applaud Elyse (President and CEO Elyse I. Summers, JD) and Michelle (Executive Vice President Michelle Feige, MSW, LCSW-C) for their vision in recognizing and seizing these opportunities.

### Q. How and why did you get involved with AAHRPP?

**A.** Like so many in the research community, my first experience with AAHRPP was the accreditation process. I was the director of the health sciences IRBs at UW-Madison when the university earned its initial accreditation in 2008 and, later, when we were reaccredited. I became an AAHRPP site visitor in 2016—and then a team leader and Council on Accreditation member—because I am fascinated with systems and finding ways to do things better. I wanted to see how different organizations structured their programs and bring those improvements back to my own HRPP. (Note: Dr. Cobb gave up her site visitor-related roles when she joined the AAHRPP staff.)

I believe in the value of accreditation. I've seen the improvements that result when we take a harder look at our HRPPs and commit to continuous quality improvement. Through my work with SMART IRB, I've also seen how AAHRPP has changed the conversation and increased organizations' willingness to rely on each other for IRB reviews. With AAHRPP, protecting research participants is a shared responsibility across the accredited institution. So, when AAHRPP-accredited organizations agree on single IRB review, it's not IRBs relying on IRBs. It's institutions relying on like institutions that have common goals and standards. That played a key role in alleviating anxiety and facilitating single IRB review.

### Q. What attracted you to this new position?

**A.** In part, it was my experience with SMART IRB, which gave me an opportunity to have a broader impact on human research protections. Instead of affecting one institution, SMART IRB affects many. AAHRPP provides that same opportunity.

Most of us are drawn to this field because we are passionate about it. With AAHRPP and SMART IRB, I get to work with some of the smartest, kindest, and most dedicated individuals on something that really matters. That's extremely gratifying.



# 20 Years of Protecting Participants, Advancing Research

This year marks the 20th anniversary of AAHRPP's founding, a pivotal event in the evolution of research protections in the United States and around the globe.

AAHRPP was established in April 2001, after a series of high-profile incidents drew national media and government attention to the need for stronger protections for research participants and better oversight of research involving humans. Leaders in the research community responded with an alternative to increased regulation: a voluntary, peer-driven accreditation process that would help organizations improve their research programs and drive best practices.

In 2002, AAHRPP officially launched its accreditation program. The first accreditations were awarded a year later—and research participants, organizations, and the general public have been reaping the benefits ever since.

Together, AAHRPP and AAHRPP-accredited organizations have helped transform the research enterprise by enhancing research protections, improving the safety and quality of research, and advancing the science that makes progress possible.

During its first 20 years, AAHRPP has:

- **Led the charge for comprehensive, systematic human research protection programs (HRPPs).** For decades, IRBs bore the primary responsibility for protecting research participants. That changed in large measure with AAHRPP accreditation and its requirement that organizations have robust research protection programs. To earn the AAHRPP gold seal, organizations must demonstrate that the entire HRPP meets accreditation standards—and that protecting research participants is a shared organizational priority.
- **Served as a convener and resource in addressing new challenges.** AAHRPP routinely brings organizations and individuals together to tackle the most pressing research-related issues. AAHRPP conferences and webinars helped the research community prepare for the first significant update of the Common Rule since 1991, adapt to new requirements for single IRB review of multisite studies, and identify and address concerns related to new technologies, such as CRISPR gene

editing and biobanking. During the COVID-19 pandemic—the worst public health crisis in recent history—AAHRPP provided leadership and support to accredited and not-yet-accredited organizations alike.

- **Introduced metrics to assess and encourage quality improvement.** AAHRPP metrics help track the progress of HRPPs, showcasing strengths and identifying areas for improvement. AAHRPP also makes those data available for research organizations, researchers, sponsors, government agencies, research participants, and other interested parties (2020 metrics coming soon). Information includes types of research conducted, audits, deviations, complaints, and IRB resources and review times.
- **Made significant progress toward establishing one standard worldwide.** From the outset, AAHRPP has taken a global perspective, designing standards that apply to research organizations within and beyond the U.S. Today, AAHRPP has accredited organizations in every sector of the research enterprise, including academic medical centers and research-intensive universities, government agencies and departments, health systems and community hospitals, contract research organizations, independent IRBs, and research institutes. In addition, AAHRPP has accredited organizations around the world—in Australia, Belgium, Brazil, Canada, China, India, Jordan, Mexico, Republic of Korea, Saudi Arabia, Singapore, Taiwan, and Thailand.

AAHRPP enters its third decade well-positioned to extend its influence, continue to advance high-quality, ethical research, and further its vision of one standard worldwide for research protections.

Each accreditation has strengthened the research enterprise and demonstrated the effectiveness of the collegial model espoused by AAHRPP's founders. Equally important, AAHRPP's emphasis on quality and flexibility—and, above all, on safeguarding research participants—will continue to have a powerful, positive impact on the research enterprise for years to come.

## Reflecting on AAHRPP's Founding and Impact

---



*"PRIM&R and AAMC were the twin Titans. Together they provided exactly what was needed to kick-start AAHRPP and undergird its eventual success."*

Elyse I. Summers, JD  
AAHRPP President and CEO  
2013-present

---



*"PRIM&R viewed accreditation as values-driven, not rule-driven. We wanted to make sure ethics would be at the center of any accreditation standards."*

Joan Rachlin, JD, MPH  
Executive Director Emerita, PRIM&R  
PRIM&R Executive Director 1975-2014

---



*"AAMC became the driver in promoting a system of clinical research oversight that would establish high standards and leave the major decisions to those responsible for conducting the research."*

David Korn, MD  
SVP, Biomedical & Health Sciences Research, AAMC, 1997-2007

---



*"We were following the Institute of Medicine guidance and elevating human research protections from simply an IRB activity to a comprehensive program within the organization. It was a completely different way of thinking."*

Marjorie A. Speers, PhD  
AAHRPP Founding President & CEO  
2001-2013

---



*"My last site visit was at an organization that had been temporarily shut down by NIH 10 years before. The site visit brought tears to my eyes—the improvement was everything I'd dreamed accreditation could achieve."*

Susan S. Fish, PharmD, MPH  
AAHRPP Site Visitor, 2001-2010  
Oversaw organizational development of AAHRPP &  
drafting of PRIM&R accreditation standards, 1999-2000





*“Fifty years from now, people will not remember the individuals involved in founding and growing AAHRPP. But people around the world will know of and continue to benefit from AAHRPP accreditation.”*

Jeffrey Cooper, MD, MMM  
AAHRPP VP for Education/Regulatory Affairs  
2002-2008

## THANK YOU, FOUNDING MEMBERS

On our 20th anniversary and always, AAHRPP honors our Founding Members for their foresight, support, and enduring commitment to research participants and high-quality, ethical research.

Association of American Medical Colleges  
Association of American Universities  
Association of Public and Land-grant Universities (formerly the National Association of Public and Land Grant Universities)  
Consortium of Social Science Associations  
Federation of American Societies for Experimental Biology  
National Health Council  
Public Responsibility in Medicine & Research

## Educating Participants About Accreditation

We have created a brochure for AAHRPP-accredited organizations to help research participants understand how accreditation sets organizations apart.

“How are You Protected? AAHRPP Accreditation” emphasizes the extra safeguards participants can expect from accredited organizations. Designed specifically for those considering volunteering for a study, the brochure highlights the robust program of protections required to achieve—and maintain—AAHRPP accreditation.

AAHRPP-accredited organizations can print [brochures](#) as needed by requesting a PDF.

