

# AAHRPP ADVANCE

One Standard Worldwide

WINTER 2021

## From the President and CEO

AAHRPP President and CEO Elyse I. Summers, JD, highlights the collegiality, determination, and innovation behind the research community's successful efforts to continue to advance research and protect participants during a period of crisis.

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## Reaching Out to Vulnerable Populations During the Pandemic

For researchers and providers at MGH Chelsea HealthCare Center, the pandemic presented an unexpected opportunity to help reduce health disparities by engaging vulnerable populations in potentially beneficial COVID-19-related research.

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## Effective Outreach Strategies

Socioeconomic factors, language barriers, and mistrust are just some of the obstacles to engaging underrepresented communities in research. Experts from two AAHRPP-accredited organizations share strategies for overcoming these hurdles. [LEARN MORE](#)

## Regaining and Sustaining Trust

Years after a dispute with the Havasupai Nation, The University of Arizona is helping set the standard for engaging Native Nations in community-based participatory research. The university has built relationships with most of Arizona's 22 Native American tribes, designating partners and establishing processes based on each tribe's preferences. [LEARN MORE](#)

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## INSIDE

2 From the President & CEO

3 Reaching Vulnerable Populations

4 Effective Strategies

5 Regaining and Sustaining Trust

### LATEST ACCREDITATIONS

- **Castle Institutional Review Board**, St. Louis, Missouri
- **Florida Health Sciences Center, Inc.**, doing business as Tampa General Hospital, Tampa, Florida
- **President and Fellows of Harvard University**, Cambridge, Massachusetts

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### OF NOTE

**Coming Soon:** New AAHRPP Element on emergency preparedness.

**Save the Date:** Join us online May 18-20 for the 2021 AAHRPP Annual Conference: Real Research in a Virtual World.

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# From the President and CEO

## *Tackling Old and New Challenges Together*

It's been nearly a year since life as we knew it was upended by COVID-19. Few, if any, of us have escaped the concerns and anxieties of the pandemic. Many in the research community feel the added responsibility of tackling both the medical challenges of COVID-19 and the longstanding issue of inequitable access to breakthrough treatments and research.

As we have so many times in the past, AAHRPP and our accredited organizations are seeking solutions together. We know that our community is remarkable for its collegiality, determination, and innovation. During this period of crisis, we are tapping those strengths to continue advancing research, protecting participants, and helping ensure that everyone benefits from the results of high-quality, ethical research.

This issue of *AAHRPP Advance* looks at a timely topic: community engagement and its role in addressing some of the disparities laid bare by the pandemic. We share the experiences and successful strategies of two accredited organizations—Mass General Brigham and The University of Arizona—that are building trust among vulnerable populations. Our February webinar, “The Importance of Community-Engaged Research: Examples of How to Implement AAHRPP Standard I-4,” also addressed this issue, as will sessions at our annual conference May 18-20.

This year, the conference will be an online event. The theme, appropriately, is “Real Research in a Virtual World.” Although the format will be new, attendees can still count on informative, thought-provoking presentations by some of the most respected experts in the research community. As in the past, AAHRPP will offer sessions for organizations that are pursuing accreditation or reaccreditation and will applaud the accomplishments of our newly accredited organizations.

It won't be the same as getting together in person, but it does offer an opportunity to “see” and interact with many of the colleagues we've been missing. The virtual event also is the latest example of the flexibility and responsiveness that are among AAHRPP's values.

From the start of the pandemic, we have acted quickly to adapt and better serve you. We issued guidance on HRPP responses to



ELYSE I. SUMMERS, JD

COVID-19, switched to remote site visits, and provided online resources, free of charge, for those seeking to attain accreditation. Soon, based on discussions with our learned colleagues, we will introduce a new Element in Standard I.1 to address the critical issue of emergency preparedness. That, too, will be covered during our annual conference.

On a final, joyful note, I want to call your attention to an AAHRPP milestone: the 20th anniversary of our founding in April 2001. So much has changed since then and, for the research enterprise, many of those changes have been for the better. We will highlight some of those accomplishments at a future date. For now, I want to emphasize how grateful we are to all of you for your contributions to our success and, even more, for your unwavering commitment to advancing research and protecting those who make it possible.

I look forward to seeing you at our virtual conference May 18-20.

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

## TACKLING INEQUITY THROUGH COMMUNITY ENGAGEMENT

AAHRPP standards have always included a requirement that accredited organizations engage the community in research. That requirement has taken on new urgency during the COVID-19 pandemic. On almost every front—including infection and mortality rates, economic impact, and access to tests and vaccines—COVID-19 is disproportionately affecting vulnerable communities. These same communities also are the least likely to participate in research and realize the resulting benefits.

AAHRPP-accredited organizations remain committed to finding innovative, effective ways to engage and protect

vulnerable populations. In this issue of *Advance*, AAHRPP features two organizations' different approaches to community engagement: Mass General Brigham's work with underserved populations in Chelsea, Massachusetts, and The University of Arizona's efforts with Native Nations.

Both approaches highlight the importance of trust, outreach, respect, and collaboration. Both also illustrate the flexibility—built into all AAHRPP standards—that enables organizations to customize their engagement efforts to meet the needs of different communities.

## Reaching Out to Vulnerable Populations During the Pandemic

For researchers and providers at MGH Chelsea HealthCare Center, the pandemic presented an unexpected opportunity to help reduce health disparities by engaging vulnerable populations in potentially beneficial COVID-19-related research.

The Mass General Brigham facility serves the City of Chelsea, a densely populated, largely immigrant community. Last spring, Chelsea was the epicenter of COVID-19 in Massachusetts. The city has remained a COVID-19 hotspot and has caught the attention of researchers eager to understand and mitigate the impact of the novel coronavirus, especially on underrepresented populations.

With support from Human Research Affairs at Mass General Brigham, the MGH Chelsea Community Research Program is helping facilitate COVID-19 studies while ensuring equity and cultural and linguistic appropriateness. Central to this effort is a new Advisory Board for Community Research, which integrates clinical specialists, healthcare administrators, and diverse community representatives.

The goal is to provide a timely pre-IRB review that balances the highest expectations for scientific and research excellence with respect for the diverse patient populations at MGH Chelsea. In other words: to meet the needs of investigators while enabling them to incorporate community concerns into COVID-19 study protocols.

“Our first commitment is to our patient population. At the same time, we want the research and investigators to be successful,” says Julie Levison, MD, MPhil, MPH, FACP, Co-Director of the MGH Chelsea Community Research Program. She also is involved in other COVID-

19-related research efforts, including as a member of the Diagnostics Working Group of the Massachusetts Consortium of Pathogen Readiness. The multi-institutional research collaboration seeks to halt the spread of COVID-19 and create a rapid-response system to address future health crises.

### An Invaluable Perspective

Dr. Levison views the community members of the MGH Chelsea advisory board as “real-world experts who know the community and its neighborhoods. They live, breathe, and work in the environment and can comment from a perspective that others on the committee simply don't have,” she says



JULIE LEVINSON, MD

That perspective can help researchers avoid missteps in a community where the language barrier can hinder informed consent. More than two-thirds of Chelsea residents are Hispanic, and about 70% of families don't speak English at home.

In addition, their experience as immigrants has resulted in concerns about privacy, along with fear and mistrust of government and other officials. Employment in lower-income “essential” jobs creates another obstacle. Taking time from work to participate in research means bringing less money home for food and other necessities.

(cont. on page 4)

This economic hardship is “one reason research is often conducted in higher-resource places,” Dr. Levison says. “In communities like Chelsea, where people’s time is so valuable, investigators should be asking, ‘What is the study giving back?’”

The answer, for COVID-19-related studies, is to advance science so providers at MGH Chelsea and elsewhere can better care for patients during a public health crisis. Longer term, the goal is to advance human health for all populations, including those in Chelsea.

Dr. Levison and her colleagues expect MGH Chelsea’s advisory board to evolve and play a role in achieving that objective. For example, members could act as trusted liaisons between community organizations and researchers, or MGH Chelsea-based clinicians and investigators could serve as co-pilots with principal investigators from outside the community. Such relationships could aid in recruiting while ensuring that studies are well-suited to the community and contribute something in return.

The MGH Chelsea team has wanted a community advisory board since launching their Community Research Program six years ago. Now, they’re determined to make the most of the board’s potential.

“It’s our COVID-19 silver lining,” Dr. Levison says.

## AAHRPP’S COMMUNITY ENGAGEMENT STANDARD

### STANDARD I-4: The Organization responds to the concerns of research participants.

- **Element I.4.A.** The Organization has and follows written policies and procedures that establish a safe, confidential, and reliable channel for current, prospective, or past research participants or their designated representatives that permits them to discuss problems, concerns, and questions; obtain information; or offer input with an informed individual who is unaffiliated with the specific research protocol or plan.
- **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.

## EFFECTIVE OUTREACH STRATEGIES

The pandemic has driven home the need to reach out to underrepresented communities so they, too, can share in the benefits of research. Yet challenges persist. Socioeconomic factors, language barriers, and mistrust are just some of the obstacles to engaging vulnerable populations in research.

How can researchers overcome these hurdles? For recommendations, AAHRPP turned to Mariette Marsh, MPA, CIP, CHPC, CHRC, Senior Director of Research Ethics and Quality at The University of Arizona, and Julie Levison, MD, MPhil, MPH, FACP, Co-Director of the MGH Chelsea Community Research Program. Both have extensive experience and success engaging underrepresented populations. Here are some of their suggestions:

**Do your homework.** Learn as much about the community as you can before reaching out. Are there conditions that make it difficult for community members to participate in research? Are there reasons—such as immigration status or prior negative experiences—for community reluctance to participate in clinical trials or other studies? What about cultural differences and expectations?

**Tap into established relationships.** Trust is fragile and takes a long time to build. Instead of approaching a community on your own, seek a community partner or colleague who already has a strong, positive connection to the community. A trusted ally can ease your introduction to the community, provide guidance, and help prevent misunderstandings and missteps that could derail the research.

**Take extra care with informed consent.** Be absolutely certain participants understand what the study involves and how the results will be used. Enlist translators, respected community members, and others who can anticipate community concerns so you can respond and, if necessary, adapt the study design.

**Be flexible and responsive.** If a community has concerns about your research processes, find ways to make adjustments. If you’re unwilling to meet the community’s needs, odds are community members will be unwilling to participate.

The process of community engagement requires patience and commitment, adjustments and negotiation. But the potential—to extend the benefits of high-quality, high-impact research to all populations—is undeniable and extraordinary.

# Regaining and Sustaining Trust

When Mariette Marsh, MPA, CIP, CHPC, CHRC, joined the Human Subjects Protection Program at The University of Arizona (UArizona) in 2006, all research with the Havasupai Nation had been halted over a dispute between the tribe and another Arizona university.

Two years earlier, the Havasupai had filed suit against the Arizona Board of Regents, charging Arizona State University (ASU) with violations during research conducted in the 1990s. While the case was being litigated, the Havasupai banished all university personnel, including UArizona's Cooperative Extension agent, and banned all engagement and research affiliated with the Arizona public university system.

This punitive action extended to UArizona because the principal investigator in the ASU study had taken a new position with UArizona, bringing her research projects, confidential data, and biospecimens from the study with her.

Today, largely because of settlement terms reached in 2010, the ban has been lifted, and UArizona guidelines help set the standard for engaging Native Nations in community-based participatory research.

- UArizona now has comprehensive policies on issues that include tribal sovereignty and authority, consultation and cooperation, informed consent, and community risk-benefit assessment.
- The strengthened UArizona Native Peoples Technical Assistance Office, within the Office of Research, Innovation and Impact, regularly engages and collaborates with Native Nations throughout Arizona and is an invaluable resource for researchers and tribal communities.
- Tribal members serve on UArizona IRBs.
- A cabinet-level position, senior vice president for Native American advancement and tribal engagement, underscores UArizona leadership's commitment to fostering partnerships and opportunities for Native Nations statewide.

Behind these efforts is a heightened appreciation for the role of trust, respect, collaboration, and shared goals in ensuring effective, community-engaged research.

"We're a Research 1 and NIH All of Us institution. If we want the community to engage with us in research, we must do it in a respectful way," says Ms. Marsh, Senior Director of Research Ethics and Quality at UArizona.

"Building trust takes time and requires outreach," she adds. "But if you're willing to invest the time, see things from a different perspective, and accept that what you propose might be modified, the working relationships, collaboration, and research results can be fabulous."

## The Importance of Accommodation

Arizona is home to 22 Native American tribes, and UArizona has worked with most to designate partners and establish processes based on each tribe's preferences. UArizona also routinely consults with tribal leaders and informs them of research activity, even if it involves tribal citizens who live outside a reservation.

Out of respect and in recognition of tribal sovereignty, Ms. Marsh and her team have made visits to Window Rock, the seat of government and capital of Navajo Nation, more than four hours from UArizona. During one visit, UArizona team members and Navajo Nation representatives collaborated on better ways to work together, addressing tribal requests for assurances, concerns about oversight, and other issues.



MARIETTE MARSH, MPA

"Our work together takes a lot of time, communication, and negotiation—and it's time well spent because it alleviates concerns on both sides," Ms. Marsh says. "In the past, tribal nations felt we were coming to conduct research without notifying them. Now, we make sure to ask questions such as, 'Do you approve of this? Do you want to be part of it? Do you have any concerns?' That has really made a difference."

## Widespread Applications

UArizona relies on similar engagement efforts to reach out to other marginalized communities, including an underrepresented rural population and Hispanic and Latino communities.

The university is located in Tucson, where more than 40% of the population is Hispanic or Latino. In addition, UArizona is a Hispanic-Serving Institution, a designation reserved for colleges and universities where more than 25% of full-time undergraduate students are Hispanic.

UArizona IRBs include Latino and Hispanic members who review research that involves their communities. These Spanish-speaking members also assist with translations and help ensure that their community genuinely understands and consents to the research.

Outreach to Latino and Hispanic communities is rooted in the same goals and principles as efforts to engage Native Nations.

"You can extrapolate what we've done with tribal nations and apply it to any group," Ms. Marsh says. "Regardless of the community, the goal is to build trust—and the place to start is with the researcher or institution going into the community and genuinely engaging them."

# 2021 AAHRPP ANNUAL CONFERENCE (REMOTE): REAL RESEARCH IN A VIRTUAL WORLD

Join us online May 18-20 for the 2021 AAHRPP Annual Conference. Once again, AAHRPP has assembled some of the most respected leaders from across the research community to share their insights on today's most pressing research issues.

Four plenary sessions will cover the following:

- Health Inequality and Social Justice in the Time of COVID
- Ethics of Emergency Use Authorizations
- The Ethical, Regulatory, and Research Complexities of Human Gene Editing – CRISPR
- Data and Privacy in 2021

The conference is open to accredited and not-yet-accredited organizations. In addition to plenary and breakout sessions, it will include a pre-conference day for organizations that are pursuing initial accreditation or reaccreditation. Watch for more details, including registration and the conference agenda, in the weeks to come. Or check for updates [online](#).

## New Element on Emergency Preparedness

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AAHRPP has been working with primary stakeholders and its Council on Accreditation on a new requirement to ensure the sustainability of human research protection programs (HRPPs)—and safeguard research participants—in the event of emergencies, such as the current pandemic.

AAHRPP's Element on Aiding Preparedness will address the preparation for and day-to-day responsibilities, roles, and expectations of organizations, researchers, research staff, IRB members, and the community during a public health crisis or emergency. The requirements will overlap all domains, as emergency preparedness efforts are an integral part of the entire organization at every level.

As with all Standards and Elements, organizations will have a great deal of flexibility in how to meet the required outcomes in this new Element. Organizations also will be expected to have reasonable plans that are proportional to the size of the HRPP and the type of research conducted—one size does not fit all HRPPs.

The new Element is expected to be added under Standard I.1; proposed language for Element I.1.H is:

**The Organization has and follows written policies and procedures specifically designed to protect the rights and welfare of research participants during an emergency.**

The new Element was prompted both by challenges that HRPPs faced during the current pandemic and by organizations' experience responding to previous disasters, including hurricanes Katrina and Sandy. The goal is to ensure that HRPPs develop and periodically evaluate plans for emergency preparedness and response as part of ongoing HRPP operations.

Watch for more information in a Tip Sheet and during the 2021 AAHRPP Annual Conference. The virtual event is scheduled for May 18-20.