

# AAHRPP ADVANCE

One Standard Worldwide

WINTER 2014

## The Benefits of Community Engagement

The more involved the community, the more likely it is to benefit from research discoveries. Learn more about AAHRPP's standards for community engagement and one accredited organization's successful community partnerships.

SEE PAGE 2

## Conference Features Research Leaders



Jeffrey R. Botkin, M.D., M.P.H., SACHRP Chair, and Chief, Division of Medical Ethics and Humanities at the University of Utah, is among the plenary speakers at the 2014 AAHRPP Conference. Join us April 23-25 in Utah.

SEE PAGE 3

## Acknowledging Our Founding Members

We begin a series of articles on AAHRPP's founding members with a look at AAMC's continued, critical role as an advocate for AAHRPP accreditation.

SEE PAGE 5

## Poised for Continued Progress In 2014



AAHRPP President and CEO Elyse I. Summers, J.D., expects steady growth across the U.S. and overseas as organizations increasingly view AAHRPP accreditation as a necessity. AAHRPP standards remain rigorous and accessible.

SEE PAGE 6

## Of Note

- 2014 AAHRPP Board Members, Officers
- Updated Metrics Reduce Reporting Burden
- Check Out Our 2014 Webinars

WINTER 2014

## INSIDE

2 Community-Engaged Research

3 AAHRPP Conference April 23-25

5 AAMC: A Permanent Partner

6 Message From the CEO

## Latest Accreditations

- **Asan Medical Center**, Seoul, Republic of Korea
- **Jiangsu Province Hospital, the First Affiliated Hospital of Nanjing Medical University**, Nanjing, China
- **McLaren Health Care Corporation**, Flint, MI
- **North Shore-LIJ Health System**, Manhasset, NY
- **Pennington Biomedical Research Center, Louisiana State University System**, Baton Rouge, LA

# Reaping the Benefits of Community Engagement

Community engagement has emerged as one of the research enterprise's top priorities—and with good reason. Experience indicates that community involvement builds public awareness and trust in research. Perhaps even more important, the more involved the community, the more likely it is to benefit from research discoveries.

Consider the Contraceptive CHOICE Project, a cohort study on reducing barriers to long-acting reversible contraception. Washington University in St. Louis (WU, AAHRPP accredited since 2004) partnered with eight community organizations and private physicians to conduct the study, which enrolled more than 9,000 St. Louis-area women between 2007 and 2011.

“Together, we created a study that focused on participants and put them first,” said CHOICE Project Director Gina Secura, Ph.D., M.P.H., Senior Scientist/Epidemiologist, WU Division of Clinical Research. “Because of that, participants remained engaged throughout the project and, after it was over, volunteered to help us disseminate the results.”

CHOICE and WU's **Community Engaged Research Program** (CEnR) are discussed below.

## AAHRPP standards, perspectives on community engagement

Since its founding, AAHRPP has asked accredited organizations to engage the community as part of the obligation to respond to the concerns of research

participants. AAHRPP Standard 1-4 (Elements 1.4.A and 1.4.B) requires organizations to make information readily available to past, current, and prospective research participants and to engage in activities that enhance the understanding of research.

A third element (1.4.C) applies only to organizations that conduct community-engaged or community-based participatory research. Element 1.4.C specifies that these organizations involve participants and community members, when appropriate, in the design and implementation of research and in the dissemination of results. The WU project discussed in this article constitutes the type of research that element 1.4.C covers.

All three elements give organizations the flexibility to develop their own approach to engagement, in keeping with the needs of a particular community. The approach should be rooted in ethical considerations—respect for persons, equitable selection of subjects, and beneficence—and should emphasize community outreach, consultation, involvement, and collaboration.

Because organizations sometimes fall short in communicating with participants and the community, AAHRPP suggests using a combination of tactics. Examples include incorporating information in consent materials, posting it online, and involving community partners in explaining the purpose of the research and how it will be conducted.

## CHOICE: Community engagement in action

The CHOICE project exemplifies an effective approach for community engagement and demonstrates the resulting benefits to the research and the community. The project also highlights the invaluable role of WU's CEnR program, which was developed by the university's Human Research Protection Office (HRPO) to assist WU researchers and ensure regulatory compliance.

“As we became more involved in community research, we recognized the need for an overall support structure, not just for our own researchers but also for our community partners,” said Martha Jones, M.A., C.I.P., Executive Director, WU HRPO.

Under the terms of the program, WU may agree to serve as the institutional review board (IRB) of record for community partners that do not have their own IRB and are engaged in research with a WU principal investigator. As the IRB of record, WU reviews the research protocols and provides human subjects training for all involved community partners. In addition, the HRPO serves as a resource for researchers and community partners throughout the course of the study.

Since launching CEnR, the HRPO has seen a change among WU researchers, who initially were concerned about possible delays in the research review process.

“They've come to realize that in the long run, partnering with other

## Reaping the Benefits of Community Engagement

parts of the institution in a very active way actually benefits the research,” Ms. Jones said. She points to CHOICE Project Director Secura as “a great example of someone who talked with the IRB from day one.”

The goals of the CHOICE project were to remove financial barriers to contraception, promote the most effective methods of birth control, and reduce unintended pregnancies in the St. Louis area. Participants were counseled about their contraception options and were provided with their birth control method of choice for up to three years.

Participants were followed throughout the study to assess satisfaction levels and birth control failure

rates. At the end of the study, women who’d chosen a long-acting reversible contraceptive method were both more satisfied and less likely to have had an unintended pregnancy.

From the beginning, Dr. Secura recognized that the success of the study would depend on the ability to recruit and retain participants. She began by reaching out to St. Louis-area health clinics and physicians, acknowledging their concerns about having researchers in their offices, seeking their input on the study design, and working with them to reduce barriers to participation. She took a similar approach with study participants.

When the study ended, Dr. Secura and her team further strengthened

their relationships with participants and community partners by involving them in disseminating the research findings. The research team emailed thank-you letters and summaries of the results to all participants and interviewed 100 on how best to communicate the findings. The team then acted on participants’ recommendations, creating a YouTube **video** and tapping participants’ connections with churches, community groups, and employers.

“We really listened to our partners and participants, engaging them on the front end, back end, and throughout,” Dr. Secura said, “and we all had a much richer experience as a result.”

## Conference Offers Latest Information, Networking Opportunities

### *Join us April 23-25 in Utah*

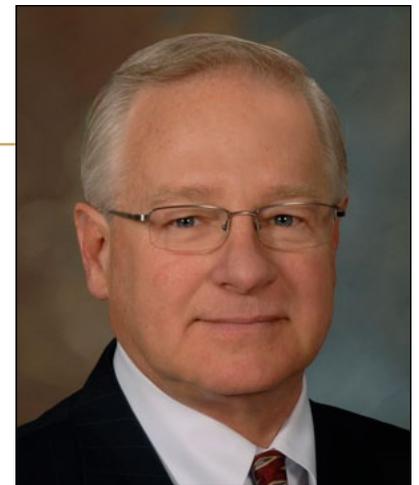
Leaders from across the research enterprise will tackle some of today’s most complex research protection issues during the 2014 AAHRPP Conference: Quality Human Research Protection Programs.

Scheduled for April 23-25 in Salt Lake City, the conference offers opportunities to network with presenters and attendees from around the globe. **Registration** is under way, with an early bird rate available through February 17.

Among the plenary speakers is Jeffrey R. Botkin, M.D., M.P.H., Chair, Secretary’s Advisory Commit-

tee on Human Research Protections (SACHRP), and Chief, Division of Medical Ethics and Humanities at the University of Utah (AAHRPP accredited since 2007). He will discuss “Reporting Results and Incidental Findings to Research Participants.”

The conference’s 35 sessions will explore this year’s theme, “Leading the Way: From the Essentials to the Cutting Edge.” Topics include data sharing and consent, ethical challenges posed by Internet research, comparative effectiveness research, and managing multiple central institutional review boards (IRBs). Information on specific sessions can be found in the **agenda**.



JEFFREY R. BOTKIN, M.D., M.P.H.

Poster presentations will highlight innovative solutions and best practices. Pre-conference workshops will be geared toward organizations that are interested in pursuing AAHRPP accreditation or are in the midst of the accreditation process.

“The AAHRPP conference is widely regarded as one of the best opportunities to hear, firsthand, about trends, issues, and advances in research protections,” said Elyse I. Summers, AAHRPP President and CEO. “This year’s sessions feature leaders from government, industry, healthcare, and academia—virtually every sector of the research enterprise.”

Dr. Botkin considers the AAHRPP conference “the ideal audience for

discussions of contemporary research issues.” His plenary session will address the controversial consequences of advances in genomic research and the resulting capability to generate large volumes of data about participants.

“The question is, as an investigator, what research results do you have a responsibility to disclose to participants?” Dr. Botkin said.

He will share his insights on the type of information that should be disclosed, as well as appropriate plans and procedures for disclosures.

## 2014 AAHRPP Conference



**2014 AAHRPP Conference**  
**April 23-25**  
**Salt Lake City, Utah**

**QUALITY HUMAN  
RESEARCH  
PROTECTION  
PROGRAMS**



**AAHRPP**<sup>®</sup>

Association for the Accreditation of  
Human Research Protection Programs, Inc.<sup>®</sup>

**“Leading the Way:  
From the Essentials  
to the Cutting Edge”**

# AAMC and AAHRPP: Permanent Partners

*This is the first in a series of articles on AAHRPP's founding members and the crucial role they've played—and will continue to play—in AAHRPP's success.*

The Association of American Medical Colleges (AAMC) has long been among the staunchest advocates for research protections, so it is only natural that AAMC was one of seven organizations to establish AAHRPP in 2001. In the years since then, AAHRPP has come into its own and earned AAMC's respect and continued support.

"We have seen enormous progress because of AAHRPP," said Ann Bonham, Ph.D., AAMC Chief Scientific Officer. "We believe there is a much stronger commitment to protect those who are willing to participate in research, and we've seen dramatic improvement in the safeguards and related resources that are in place at the institutional level.

"We consider AAMC to be a permanent partner and permanent supporter of AAHRPP," she added.

## Accreditation as self-regulation

AAHRPP was founded in response to serious, highly publicized incidents—including the death of two participants—that focused public and government attention on weaknesses in research protections. After federal agencies stepped up inspections and shut down some of the nation's most respected research programs, key members of the research community

pressed for the creation of an independent accrediting body to assess and help strengthen research programs and protections.

Public Responsibility in Medicine and Research (PRIM&R) approached AAMC, and together the two organizations obtained commitments from the Association of American Universities, the Association of Public and Land-grant Universities, the Consortium of Social Science Associations, the Federation of American Societies for Experimental Biology, and the National Health Council to help bring about the organization that would become AAHRPP.

All seven founding organizations provided start-up loans. AAMC designed the business plan and opened office space to AAHRPP leadership during the development of the first accreditation standards.

"To our Executive Council, now our Board of Directors, this was very much in keeping with AAMC's role as a leader in the research community," Dr. Bonham said. "Our elected leadership also felt strongly that the new accreditation program should be rigorous and should serve as the model for evaluating research protection programs, whether in academia, medical institutions, or private industry."

## "Changing the conversation"

In the years since, AAHRPP has lived up to and, in many instances, exceeded AAMC's expectations. Currently 74 of AAMC's 141 U.S. member organiza-

tions are AAHRPP accredited, and an additional 17 have initiated the accreditation process. AAMC continues to encourage members to earn and maintain AAHRPP accreditation.

For Dr. Bonham, the numbers tell only one piece of the story. "AAHRPP has really changed the national conversation and the way we view our responsibility and relationship with research participants," she said. "Now, regardless of our role in research—whether we're enrolling participants or designing or conducting the study—we realize that we are all accountable.

"That's a major value which AAHRPP has brought to clinical care, clinical research, and the community," Dr. Bonham added.

True to its roots, today's AAHRPP reflects the priorities of its founding members. Dr. Bonham cites AAHRPP's success in improving the efficiency and effectiveness of institutional review boards, strengthening protections for the most vulnerable, and helping to ensure that communities participate in research and share in the benefits it produces.

Looking ahead, she expects AAHRPP to address the challenges and opportunities presented by big data, help organizations understand and comply with new regulations on financial conflict of interest, and tackle the consent issues regarding future use of DNA.

"We have every reason to believe that AAHRPP will be in the forefront of the continued evolution of research protections," Dr. Bonham said.

## From the President and CEO

---

### *Poised for continued progress*

In many ways, there has never been a more exciting time for AAHRPP and those who recognize AAHRPP accreditation's role in advancing quality research, furthering scientific inquiry, and, of course, protecting research participants.

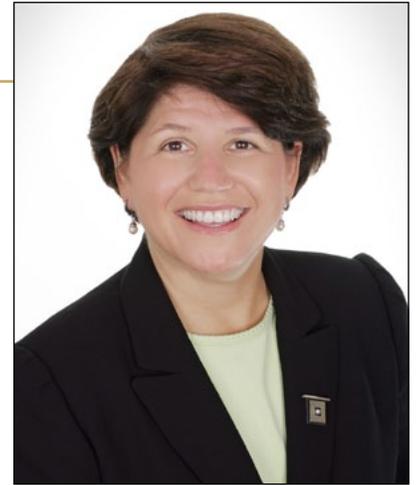
We begin 2014 poised to continue our progress in the United States and around the globe. Our most recent **accreditations**—including international organizations and major hospital and university systems—reflect growing awareness of both the universal value of AAHRPP accreditation and the shared commitment of organizations across the research enterprise.

In my first few months as AAHRPP President and CEO, I've been *doing* a ton, including a ton of listening. (My formal "listening tour" begins in February; stay tuned for more on that.) In the meantime, I want you to know that I couldn't be more encouraged by what I've been hearing. People from AAHRPP-accredited organizations and not-yet-AAHRPP-accredited organizations are telling me that they believe we have reached a tipping point. After 12 years of steady inroads, it's become increasingly clear that AAHRPP accreditation is less an option and more a necessity.

Experience has shown that the rigor of AAHRPP's standards truly has translated into stronger protections and higher quality human research protection programs (HRPPs). We see it every time we send a team out on a site visit. Team members return and tell us that AAHRPP's standards are being used exactly as intended: to build comprehensive HRPPs, where responsibility for research protections is shared throughout the organization.

The word has spread to key constituencies. Sponsors, researchers, federal agencies, and others involved in research know that there is no more objective, reliable mark of a quality program than the AAHRPP seal.

We are extremely proud of our reputation for rigor. But we also want organizations to know that AAHRPP accreditation is accessible. If you are willing to make a commitment to reach our high standards, we will work with you to help you achieve them. After all, we have the same goal: to continually improve the quality of research and research protections. And we accomplish that one accreditation at a time.



---

ELYSE I. SUMMERS, J.D.

---

It also bears mentioning that as an organization, AAHRPP is able to serve the research community today because of the support and encouragement of its seven founding members, each of which will be featured, in turn, in our *Advance* newsletter. We begin, this issue, with the **Association of American Medical Colleges**.

And no inaugural article with my name attached to it would be complete without a huge shout-out of deeply felt gratitude and congratulations to our friends at Public Responsibility in Medicine and Research (PRIM&R), a founding member and long-standing partner of AAHRPP. As many of you know, Joan Rachlin, PRIM&R's visionary and first Executive Director and a personal mentor nonpareil to me, will step down at the end of March after 39 years and turn the reins over to the fabulously talented Elisa Hurley. We salute Joan and her legacy, and we look forward to working closely with Elisa and everyone at PRIM&R—and with all of you—to take research protections to the next level.

Best regards,

A handwritten signature in blue ink that reads "Elyse I. Summers".

Elyse I. Summers  
AAHRPP President and CEO