



**AAHRPP**®

Association for the Accreditation of

Human Research Protection Programs, Inc.®

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# **AAHRPP History and Future: Yesterday, Today, and Tomorrow**

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# AAHRPP: 20 Years of Protecting Participants, Advancing Research

The Association for the Accreditation of Human Research Protection Programs (AAHRPP) was founded in April 2001 amid calls for reform of U.S. research involving human participants. Leaders in the research community responded with an alternative to increased government regulation: a voluntary, peer-driven accreditation process that would help organizations improve their research programs and drive best practices.

AAHRPP's accreditation program was officially launched in 2002. The first accreditations were awarded a year later. 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 strengthening 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, institutional review boards (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 issues related to research ethics and participant protections. 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 online for research organizations, researchers, sponsors, government agencies, research participants, and other interested parties. 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 make significant progress in achieving 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.

## A Look Back: Calls for Accountability Give Rise to Accreditation

One of the first recommendations for accreditation of research programs involving human participants was made in 1983 by the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research.<sup>1, 2</sup> It would be more than 15 years before accreditation would receive serious consideration as part of efforts to reform and strengthen protections for research participants.

Some of the earliest, most fruitful discussions about establishing an accrediting body to help protect research participants can be traced to Public Responsibility in Medicine and Research (PRIM&R). Those efforts took on new urgency in the late 1990s and early 2000s after a series highly publicized incidents—including the death of a 24-year-old healthy volunteer in a Johns Hopkins University study—raised concerns about the ethics and quality of U.S. research involving humans. U.S. officials responded by suspending federally funded medical research at some of the nation's largest, most prestigious programs.



*"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  
PRIM&R Executive  
Director Emerita

(Served as Executive  
Director 1975-2014)

The suspensions highlighted what many viewed as systemic failures to protect participants in an increasingly complex research environment. Within universities, the scientific community, government agencies, and among the general public, pressure was mounting for improved oversight and accountability, including increased transparency about research relationships. Leaders in the research community—including the Institute of Medicine (now the National Academy of Medicine) and the National Bioethics Advisory Commission—began calling for a fundamental shift in research oversight, which traditionally had been the responsibility of the IRB. Under this new model, IRBs would be part of a comprehensive HRPP designed to share accountability throughout the research organization.

In fall 1999, PRIM&R convened a series of meetings of highly respected professionals from across the research enterprise to take on the challenge of creating an accrediting body for HRPPs. The group established three committees: one each to develop the organizational structure, the financial model, and performance standards for HRPPs. The goal was to create the framework for an accrediting body that PRIM&R could then spin off as a separate organization. In March 2000, PRIM&R incorporated the accrediting body in PRIM&R's home state of Massachusetts under the name the Association for the Accreditation of Human Research Protection Programs (AAHRPP).

At about the same time, after the first-ever shutdown of research at a Department of Veterans Affairs (VA) health system, the VA also was focused on accreditation. In April 2000, the VA contracted with the National Committee for Quality Assurance (NCQA) to develop a research accreditation program for VA medical centers.

Throughout these early accreditation development efforts, research programs remained under scrutiny, and calls for reform were intensifying. The research community was becoming increasingly concerned both about quality and safety issues affecting research participants and the potential negative impact of additional government oversight. Within the research enterprise, accreditation began to be perceived as a more attractive, more viable option. One of the most influential organizations, the Association of American Medical Colleges (AAMC) took up the charge and began advocating for a voluntary, peer-reviewed accreditation program. AAMC was confident that, with support from the ground up, accreditation could prove effective in setting high standards, advancing high-quality ethical research, and protecting research participants. The



*“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

approach would be affirmative rather than punitive, with a familiar model similar to those of the American Association for Accreditation of Laboratory Animal Care and Middle States Commission on Higher Education.

AAMC prevailed in persuading six additional organizations to sign on, including PRIM&R, which demonstrated its support in part by providing the AAHRPP name. In April 2001, AAHRPP was incorporated in Baltimore with AAMC as the signatory. Joining AAMC as founding members were PRIM&R, the Association of American Universities (AAU), 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, and National Health Council. Together, these organizations brought diverse perspectives—of bioethicists, IRB professionals, patient advocates, investigators, and research institutions—to the fledgling accreditation enterprise.

## The Early Years: 2001-2005

The founding members moved quickly to develop new accreditation standards and name an executive director<sup>3</sup>. In August 2001, after a nationwide search, Marjorie A. Speers, PhD, was chosen as AAHRPP’s first leader, effective October 1 of that year. Dr. Speers came to AAHRPP from the National Bioethics Advisory Commission, where she served as acting executive director on detail from the Centers for Disease Control and Prevention (CDC). At the CDC, she was deputy associate director for science, responsible for human research protection for all domestic and international research.

AAHRPP's accreditation program—including comprehensive standards, a council on accreditation, and a team of site visitors—was officially launched in 2002. The AAHRPP standards reflected the recommendations of the 2001 Institute of Medicine report, "Preserving Public Trust: Accreditation and Human Research Participation Protection Programs," which cited accreditation by an independent entity as one potential tool for strengthening research protections. The standards also were rigorous—meeting and, in some cases, exceeding U.S. regulations—yet broad and flexible, recognizing that organizations could take different but equally successful approaches to fulfill the same requirements. Equally important, the standards emphasized that the responsibility for protecting research participants is shared by the entire research community, beginning with institutional leadership and extending to the most junior staff.

Unlike the NCQA program, developed exclusively to accredit VA programs, AAHRPP accreditation was available to the full complement of research entities, including: universities, hospitals, government agencies, contract research organizations, sponsors, and independent IRBs. In keeping with the increasingly global nature of the research enterprise, AAHRPP standards also were designed to apply to research programs beyond the U.S.

During these early years, AAHRPP benefited considerably from the support, experience, and reputation of its founding members, tapping their expertise to appoint its inaugural board of directors, council on accreditation, and team of site visitors. Spurred in part by their connection to the founding members, six organizations—The University of Iowa, Western Institutional Review Board, New England Institutional Review Board, Hunter Holmes McGuire Veterans Affairs Medical Center, Baylor Research Institute, and Catholic Medical Center—stepped up and officially committed to pursuing AAHRPP accreditation. These six organizations were the first to conduct the comprehensive self-assessments, the first to submit the extensive accreditation application, and the first to undergo the rigorous AAHRPP site visit. In 2003, they made history as the first organizations to earn AAHRPP accreditation. (All remain accredited today, some under the names of their successor organizations.)

2003 also brought the challenge of a competitor. NCQA, already under contract to accredit VA research facilities, partnered with the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) to launch the Partnership for Human Research



*"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



Protection (PHRP). Like AAHRPP, this new organization offered accreditation to all organizations engaged in research involving human participants. The partnership would last just two years. PHRP shut down November 1, 2005, after accrediting nine organizations. Officials cited a lack of interest in accreditation.<sup>4</sup>

During the same period, AAHRPP accreditation was beginning to take hold. By year-end 2005, more than 30 organizations representing over 90 entities nationwide\* had earned AAHRPP accreditation. Among them were community hospitals, teaching hospitals, and cancer centers; independent IRBs; research institutes; and universities. Another 210 organizations—including U.S. government entities—had begun the AAHRPP accreditation process. And nearly 300 research professionals attended AAHRPP’s first annual conference, which focused on quality HRPPs. Presenters included officials from the CDC, Office for Human Research Protections (OHRP), National Institutes of Health (NIH), and the Pharmaceutical Research and Manufacturers of America.

One of the most significant accomplishments of those early years came in December 2005, when AAHRPP won a five-year, \$4.9 million contract from the VA to accredit its research centers throughout the U.S. The VA decision dealt a major blow to NCQA, which had been the VA’s accrediting body since 2000 but had struggled to meet accreditation targets. NCQA and JCAHO had dissolved their PHRP accreditation program one month earlier, in November 2005. With the loss of the VA contract, NCQA no longer offered HRPP accreditation services. AAHRPP became the nation’s sole accrediting body for research programs involving human participants.



*“We were following the IOM 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 President & CEO

## Reshaping the Research Enterprise: 2006-2012

Over the next few years, AAHRPP made significant inroads throughout the research enterprise, accrediting organizations across the U.S. and, increasingly, in international markets. U.S. accredited organizations included hospitals, health care systems, academic medical centers, dedicated research sites, contract research organizations (CROs), independent IRBs, VA centers, government institutions, and research sponsors.

Among the highlights:

- The first international organization, Samsung Medical Center in the Republic of Korea, earned AAHRPP accreditation in 2006. Slowly but steadily, organizations in Canada, China, Mexico, India, and Taiwan followed.
- Pfizer became the first pharmaceutical company to earn AAHRPP accreditation, beginning in 2009 with the accreditation of the company’s three phase 1 clinical research units. (By 2013, all Pfizer research sites were AAHRPP accredited.)
- In 2012 the National Cancer Institute Central Institutional Review Board became the first NIH entity to earn AAHRPP accreditation.
- 91 VA facilities earned AAHRPP accreditation from 2007 through 2012.



*“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 organizations could achieve.”*

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

Equally important, as the pace of AAHRPP accreditation continued, so did its impact on the research enterprise. Site visitors noted dramatic improvements in HRPPs that earned accreditation. Even more striking was the difference in quality between accredited and nonaccredited organizations.

AAHRPP was instrumental in building a culture of compliance by promoting shared responsibility for research protections and advancing the concept of a comprehensive, systematic HRPP. Spurred, in part, by AAHRPP’s accreditation standards, research organizations bolstered education programs, standardized and documented research policies and procedures, and engaged researchers in quality improvement. As part of those efforts, AAHRPP and AAHRPP-accredited organizations adopted metrics to assess quality improvement measures and set higher goals.

Within accredited organizations, HRPPs attained greater visibility and respect. Administrators, faculty, and students gained increased awareness of the HRPP and their own responsibility to protect research participants. Better understanding of the federal regulations resulted in fewer protocol deviations and incidents of noncompliance. AAHRPP metrics through 2011 indicated that accredited organizations were significantly less likely to receive determination letters from OHRP or the Food and Drug Administration (FDA).

As more and more organizations earned accreditation, perceptions changed. AAHRPP accreditation evolved from a distinction attained by the few



to an expectation—and even a prerequisite—for those interested in engaging in collaborative, multisite research. Given the choice between an accredited or nonaccredited partner, AAHRPP-accredited organizations consistently began opting for the former.

AAHRPP also faced one of its greatest challenges during this period. In March 2012, the contract for accrediting VA research facilities was awarded to Alion. A defense contractor and newcomer to accreditation, Alion priced accreditation services significantly lower than AAHRPP.<sup>5</sup> The VA decision was a disappointment. Even so, AAHRPP remained positioned not only to endure but also to continue to grow. Ultimately, the VA severed its contract with Alion over the company's failure to deliver. In the years since, instead of having research facilities earn accreditation, the VA Office of Research Oversight has conducted its own compliance assessments known as combined program reviews. Nevertheless, a handful of VA research sites remain committed to maintaining their status as meeting the gold standard for research protections and, through independent funding, have consistently successfully pursued AAHRPP reaccreditation.

## AAHRPP 2.0: 2013 – Present

In February 2013, Dr. Speers announced her plans to retire by year-end. Under her leadership, AAHRPP accreditation had become the norm in the U.S. and was beginning to take root abroad. More than 180 organizations representing over 1,000 entities had earned AAHRPP accreditation. In addition, 60% percent of U.S. research-intensive universities and 75% percent of U.S. medical schools were either AAHRPP accredited or had begun the accreditation process.\*

After a national search, the board of directors selected Elyse I. Summers, JD, as AAHRPP's next president and CEO, citing her extensive experience helping organizations understand and comply with federal regulations on human research protections. In positions with OHRP, FDA, and AAU, Ms. Summers had developed and evaluated policies and procedures for HRPPs, delivered training, overseen compliance, and assessed quality. She'd also served as an expert liaison to national and international human research committees, commissions, and professional organizations. In addition, Ms. Summers had close working relationships with key AAHRPP stakeholders.

Ms. Summers took the helm at AAHRPP on October 14 with the goal of transitioning the successful startup to "AAHRPP 2.0" to meet the challenges of an increasingly complex research environment. Priorities included:

- Making accreditation more accessible, especially to smaller organizations seeking to enhance the quality of their HRPPs and raise their profile with potential research partners. AAHRPP shifted its messaging, emphasizing that it would help committed, "not-yet-accredited" organizations achieve AAHRPP accreditation.

- Continuing AAHRPP’s march across the globe to advance the vision of “one standard worldwide” for research quality and protections for participants.
- Enhancing AAHRPP’s position as a thought-leader and convener—in part by reinvigorating partnerships with its founding members and other organizations—to help research organizations address new operational and ethical challenges. AAHRPP saw an expanded, complementary role for the organization as a repository of trusted information and a resource for accredited and not-yet-accredited organizations alike.
- Bolstering reserves to support investments in technology to streamline the accreditation process, facilitate communications, and improve the overall customer experience.

AAHRPP has since made significant progress on all fronts. Accreditations have continued at a steady pace and included the first AAHRPP-accredited organization in Africa, Australia, the Gulf Arab States, and South America. In the U.S., newly accredited organizations included the NIH, U.S. Department of Energy, and first U.S. Department of Defense facility; the first historically Black college and university medical school; and two world-renowned cancer centers. As a result, today AAHRPP has accredited organizations across the U.S. and in Australia, Belgium, Brazil, Canada, China, India, Jordan, Mexico, Republic of Korea, Saudi Arabia, Singapore, Taiwan, and Thailand.

Through conferences, webinars, and other outreach efforts, AAHRPP helped research organizations navigate the first significant update of the Common Rule since 1991, including new federal requirements for single IRB review of multisite studies. AAHRPP has also convened experts to help organizations understand and address issues related to technological advances including CRISPR gene editing, biobanking, Big Data, and social media research. A new initiative, the Collaborative AAHRPP Network (CAN), was launched in spring 2019 to foster collaboration among AAHRPP-accredited organizations in a collegial, peer-to-peer setting.

During the COVID-19 pandemic, AAHRPP acted quickly to adapt and better serve accredited and not-yet-accredited organizations. AAHRPP issued guidance on HRPP responses to COVID-19, switched to remote site visits, and provided online resources, free of charge, for those seeking to attain accreditation. AAHRPP showcased its accreditation standard on community engagement and its role in addressing some of the inequities laid bare by the pandemic. In addition, AAHRPP updated its standards to include an element addressing the critical issue of emergency preparedness.

Many of these efforts stemmed from a five-year strategic plan, which is undergirded by four pillars of success: Operational Efficiency, Promoting Relationships, Achieving

Reasonable and Responsible Growth, and Demonstrating Impact. Together, these pillars have increased AAHRPP's visibility and elevated its reputation as a source of support to organizations as they seek to attain accreditation and continually improve their HRPPs.

## A Promising Future

Looking ahead, AAHRPP is poised for further growth and impact. The organization remains the only accrediting body for HRPPs in the U.S. and the gold standard for research protections around the globe. AAHRPP's response to the pandemic and other challenges has increased the organization's stature as a thought-leader and showcased the advantages of being connected to the AAHRPP-accredited community.

Twenty years after they were developed, AAHRPP's rigorous yet flexible accreditation standards remain as valuable and relevant as ever. Recent investments in technology will clear the way for a streamlined, electronic application process and will support increased outreach and collaboration.

AAHRPP will expand its influence as an educational partner and use that platform to continue to advance high-quality, ethical research. Above all, AAHRPP will remain a staunch advocate for the human participants who make research possible. As it has from the beginning, AAHRPP will work tirelessly to help protect all human research participants from unnecessary harm—and will pursue this vision by upholding the time-tested principles of respect, beneficence, and justice.



*"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

## Acknowledgements

AAHRPP is indebted to the following individuals and organizations for their commitment to AAHP and accreditation and their willingness to share their recollections for this 20<sup>th</sup> anniversary/history project.

Jeffrey Cooper, MD, MMM  
AAHRPP Vice President for Education and Regulatory Affairs<sup>3</sup>  
2002-2008

Susan S. Fish, PharmD, MPH  
AAHRPP Site Visitor, 2001-2010  
In 1999-2000, took a sabbatical to spearhead the organizational development of AAHRPP and the drafting of PRIM&R accreditation standards

David Korn, MD  
AAMC Senior Vice President for Biomedical & Health Sciences Research, AAMC  
1997-2007

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

Marjorie A. Speers, PhD<sup>3</sup>  
AAHRPP President & CEO  
2001-2013

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

### **AAHRPP Founding Members**

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

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\*Note: Mergers and consolidations of hospitals, health care systems, and independent IRBs prevent “apples-to-apples” comparisons of the numbers of past and current accredited organizations.

<sup>1</sup>Testimony of Kenneth W. Kizer, MD, MPH, undersecretary for health, Department of Veterans Affairs, on oversight of research in the Veterans Health Administration before the Subcommittee on Oversight and Investigations and the Subcommittee on Health of the Committee On Veterans' Affairs, U.S. House of Representatives April 21, 1999. (New Initiatives/ External Accreditation/3<sup>rd</sup> paragraph).  
<https://www.va.gov/OCA/testimony/hvac/sh/21AP9910.asp>.

<sup>2</sup>Implementing Human Research Regulations: The Adequacy and Uniformity of Federal Rules and Their Implementation, the President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, page 114, The Accreditation Model.

<sup>3</sup>In 2008, the “executive director” and “deputy director” titles were updated to “president and CEO” and “vice president for education and regulatory affairs,” respectively.

<sup>4</sup>“PHRP bows out of accreditation; AAHRPP left as sole accreditor,” hcPro, Vol. 4 #11, November 2005.

<sup>5</sup>“The New Kid on the Block,” December 12, 2013, infoEdge,  
<http://www.researchadministrationdigest.com/new-kid-block/>.