

The Association for the Accreditation of Human Research Protection Programs: 15 years of emphasizing research safety, ethics, and quality

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Abstract: This year marks the 15th anniversary of the founding of the Association for the Accreditation of Human Research Protection Programs (AAHRPP), an organization that has been instrumental in strengthening protections for research participants. AAHRPP was established by seven Founding Members in response to a series of high-profile incidents that shook the foundation of the U.S. research enterprise. The Founding Members viewed voluntary accreditation as one way to strengthen research protections and restore and preserve public trust. Today, AAHRPP accreditation is widely regarded as the gold standard for research protections. To attain accreditation, organizations must demonstrate that they adhere to rigorous standards covering three domains: The Organization, The Institutional Review Board or Ethics Committee, and Researcher and Research Staff. The emphasis is on system-wide policies and procedures that strengthen an organization's commitment to participants and help ensure a more consistent, more effective approach to protecting them. Because AAHRPP accreditation is considered an objective indicator of quality, the benefits to accredited organizations can be considerable. Their accreditation status sends a signal — to potential research partners, to sponsors and other funders, and to research participants — that the organization has the systems in place to conduct research in a scientifically and ethically sound manner.

Keywords: HRPP, research participants, research subjects, IRB, ethics committee, clinical research, accredited organization

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Received: May 18, 2016; **Accepted:** June 6, 2016; **Published Online:** July 29, 2016

Citation: Summers E I, The Association for the Accreditation of Human Research Protection Programs: 15 years of emphasizing research safety, ethics, and quality. *Journal of Medicines Development Sciences*, vol.2(1): 38–42. <http://dx.doi.org/10.18063/JMDS.2016.01.003>.

1. Introduction

This year marks the 15th anniversary of the founding of the Association for the Accreditation of Human Research Protection Programs (AAHRPP), an organization that has been instrumental in championing and strengthening protections for research participants. AAHRPP was established during a period of considerable concern over the state of

U.S. research protections. The goal was to develop a voluntary accreditation program that would encourage research organizations to commit to high standards and, ultimately, raise the bar for research protections. In essence, the research community came together to create AAHRPP in an effort to take ownership of these critical issues and police itself.

At the time, some voiced doubts about the effectiveness of a voluntary accreditation program. In the

years since, however, AAHRPP accreditation has taken hold throughout the United States and is making inroads around the globe. Today, AAHRPP accreditation is very much the gold standard for research protections. As of May 2016, 227 organizations have earned accreditation; 32 are located outside the United States. AAHRPP has accredited organizations in 46 U.S. states and in Belgium, Canada, China, India, Mexico, Republic of Korea, Saudi Arabia, Singapore, Taiwan, and Thailand. All major U.S. independent institutional review boards (IRBs) have earned AAHRPP accreditation. In addition, more than 60% of U.S. research-intensive universities and over 65% of U.S. medical schools are either AAHRPP accredited or have begun the accreditation process. The intramural research program of the U.S. National Institutes of Health (NIH), the world's largest public funder of research, has earned accreditation, as has Pfizer, Inc., the largest industry sponsor of clinical research.

Furthermore, AAHRPP's influence extends beyond accredited organizations. AAHRPP's emphasis on a comprehensive, systematic approach to research protections has played a key role in the fundamental shift to organization-wide responsibility for research ethics and oversight. As a result, comprehensive human research protection programs (HRPPs) are now considered central to a quality research program. In addition, increasing acceptance of AAHRPP standards as the world's standards is facilitating collaboration and laying the foundation for a global infrastructure built on a shared commitment to ethical practices.

2. Responding to Calls for Change

For the U.S. research community, the late 1990s and early 2000s will long be remembered for a number of high-profile research protection deficiencies, followed by corrective action. One of the most serious failures resulted in the death of Jesse Gelsinger, a student enrolled in a gene-transfer trial at the University of Pennsylvania, on September 17, 1999. The Gelsinger case shined a spotlight on issues including informed consent, investigator conflict-of-interest, and reporting of adverse events. The case also prompted congressional hearings on the safety of U.S. clinical trials and contributed to calls for fundamental improvements to safeguard participants and restore public confidence in research. Two entities, the non-profit Institute of Medicine (IOM)^[1] (now the National Academy of Medicine) and the National Bioethics Advisory Commis-

sion^[2] issued reports acknowledging that accreditation offered promise as part of a multipronged solution.

Seven highly respected organizations — the Association of American Universities (AAU), Association of American Medical Colleges, Association of Public and Land-grant Universities, Consortium of Social Science Associations, Federation of American Societies for Experimental Biology, National Health Council, and Public Responsibility in Medicine and Research — led the charge to establish AAHRPP. These “Founding Members” incorporated AAHRPP in April 2001, the same month the IOM issued its report, *Preserving Public Trust: Accreditation and Human Research Participant Protection Programs*. Six months later, AAHRPP opened for business and began developing its accreditation standards. They were released in February 2002, and the first accreditations followed 14 months later.

From the beginning, AAHRPP promulgated the position, espoused by the IOM^[1] and Founding Member AAU^[3], that the obligation to protect research participants rests with the entire organization, not just the IRB or ethics committee (EC). In fact, many credit the IOM with coining the term “HRPP,” which has come to define today's approach to research protections. In its April 2001 report, the IOM advocated for “a broader human research participant protection system than just the IRB, with multiple functional elements that in total are referred to as human research participant protection programs, or HRPPs”^[1]. AAHRPP's accreditation standards reflect that systematic approach, which is spelled out, up front, in Standard I-1:

“The Organization has a systematic and comprehensive Human Research Protection Program that affords protections for all research participants. Individuals within the Organization are knowledgeable about and follow the policies and procedures of the Human Research Protection Program”^[4].

AAHRPP standards are also designed to apply to the broad range of organizations engaged in overseeing research involving humans, from nonprofit hospitals and academic medical centers to for-profit IRBs and pharmaceutical companies. That universal application was evident almost immediately. Among the first 10 organizations to attain AAHRPP accreditation were three independent IRBs, a veterans medical center, three academic institutions, and three hospitals. In the years since, government agencies, contract research

organizations, dedicated research sites, research institutes, and sponsors have all joined the ranks of AAHRPP-accredited organizations.

3. A Collegial, Transparent, and Rigorous Process

The AAHRPP accreditation process is voluntary, collegial, and transparent. It is a peer-to-peer review — not an audit of ethics decisions or individual studies. Because the focus is on quality and outcomes, the process is flexible. It acknowledges that there are many possible avenues to achieve the shared goal of protecting the health and welfare of research participants, without whom the research enterprise could not exist. The accreditation process also is rigorous and reflects AAHRPP's recognition that today's complex research environment requires a program of systematic and complementary protection functions. Furthermore, the process emphasizes that the obligation to fulfill those functions is shared across the research organization.

In keeping with that emphasis, AAHRPP organizes its standards according to three domains^[4].

- **Domain I: The Organization** covers organization-wide policies on financial disclosures, clinical trial provisions, education and training in research ethics, scientific review, community engagement, and plans for quality improvement.
- **Domain II: The IRB or EC** covers the review function, including the composition of the IRB/EC, the existence and application of policies consistent with regulatory review criteria, additional protections for vulnerable participants, procedures for handling unanticipated problems, and appropriate documentation.
- **Domain III: Researcher and Research Staff** focuses on the qualifications and actions of those engaged in the research. Domain III standards assess whether the researcher and research staff know the ethical standards relevant to their discipline and to the protection of the rights and welfare of research participants, know the reporting requirements, are responsive to the questions or concerns of participants, appropriately oversee the research, and adhere to the protocol and organizational policies.

The accreditation process is designed to be educational, to help applicants identify the strengths and weaknesses of their HRPPs and target specific areas for improvement. The process begins with a comprehensive self-assessment that enables organizations to

make improvements long before the on-site evaluation that is required for all accreditation applicants. Organizations conduct the self-assessment using the same evaluation instrument that site visitors will rely on later in the accreditation process. AAHRPP offers a variety of resources, including tip sheets and webinars, to help guide applicants through the self-assessment and the rest of the accreditation process.

AAHRPP reviews the self-assessment and other application materials and, if they are complete, schedules an on-site visit. This, too, is meant to be educational and collaborative. Site visitors meet with the organization's accreditation team, interview individuals involved in the organization's HRPP, review sample documents, raise potential issues, and point out areas of strength or in need of improvement. The site visit team also prepares a draft report to give organizations the opportunity to respond to and rectify any issues raised. Once this response is received, the site visit team makes its recommendation to the AAHRPP Council on Accreditation.

AAHRPP's philosophy is to encourage organizations to pursue accreditation as a means to improve their HRPPs and the quality of their research. Therefore, if an organization is committed to accreditation, AAHRPP will do everything possible to help the organization meet the accreditation standards and achieve the accreditation goal. Accredited organizations renew their accreditations three years after the initial accreditation and every five years thereafter. To ensure continued compliance with AAHRPP standards, organizations applying for reaccreditation perform the same self-assessment and gap analysis required for the initial accreditation application.

3.1 Measurable Results

The benefits of AAHRPP accreditation are considerable — for research participants, accredited organizations, and the research enterprise as a whole. The emphasis on system-wide policies and procedures strengthens an organization's commitment to participants and helps ensure a more consistent, more effective approach to protecting them. Because AAHRPP accreditation is widely regarded as an objective indicator of quality for HRPPs, accredited organizations gain the respect of their peers and often are chosen to take the lead on collaborative research efforts. AAHRPP-accredited organizations often have more efficient operations, continuously improve with an eye toward providing more comprehensive protections, and

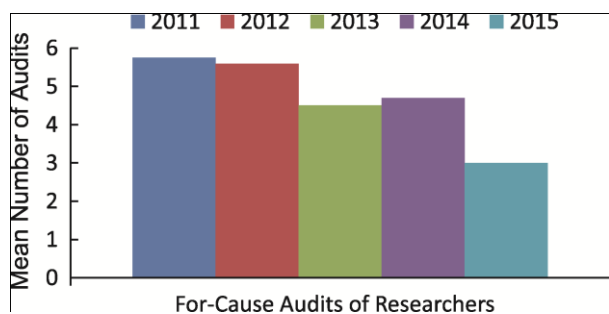


Figure 1. Five-year trends in mean number of audits organizations conducted. Since 2011, there has been a decrease in for-cause audits of researchers at AAHRPP-accredited organizations, indicating improvements in quality.

produce high-quality data. Tethered to the fulfillment of accreditation standards, these organizations tend to keep robust records and have been generally more likely to avoid costly shutdowns and problematic inspections. As a result, AAHRPP-accredited organizations may have a competitive edge with sponsors and other funders.

In 2010, AAHRPP began publishing metrics on HRPP performance based on data supplied in clients' annual reports and by new applicants for accreditation. The data cover topics ranging from types of research and conformance with regulations and guidance to financial and personnel resources and IRB review times. The 2015^[5] metrics are available at www.aahrpp.org. An example of the type of information that AAHRPP tracks is provided in Figure 1, above.

One benefit of AAHRPP accreditation — trust and respect among research partners — is more difficult to quantify but has become increasingly important in a research enterprise that is moving toward single or central IRB review of multisite studies. In the United States, the National Cancer Institute and National Institute of Neurological Disorders and Stroke already rely on central IRBs, and the NIH has issued a draft policy that, when made final, will require single use of IRBs for some or all NIH-funded multisite U.S. studies. A similar requirement is included in the proposed revisions to the Common Rule, the U.S. policy for the protection of human research participants. Action on those revisions is expected later this year.

To earn AAHRPP accreditation, an organization must demonstrate that it has the necessary infrastructure, or HRPP, to ensure that research is conducted in a scientifically and ethically sound manner. Organizations that earn AAHRPP accreditation, and the right to display the AAHRPP seal, deliver an important message: They have the systems in place to protect par-

ticipants and comply with all rules and regulations. In other words, AAHRPP-accredited organizations can be trusted to serve as the IRB of record. This assurance helps alleviate concerns about ceding oversight to another organization and, therefore, can facilitate the single IRB review that many regard as essential if the research enterprise is to succeed in streamlining the research review process while maintaining the highest possible standards.

4. Looking Ahead: Serving the Research Enterprise as AAHRPP 2.0

The 15 years since AAHRPP's founding have brought significant changes to the research enterprise, and AAHRPP has responded accordingly. AAHRPP was quick to recognize the increasingly global nature of the research enterprise and had the foresight to develop standards that apply equally well to organizations of all sizes and all nations. In 2007, National Healthcare Group of Singapore became the first non-U.S. entity to earn AAHRPP accreditation. The number of international accreditations has grown steadily ever since. In response to strong interest from organizations in Asia, AAHRPP has translated its standards into simplified Chinese. In addition, the 2015 annual AAHRPP conference included a session conducted in Mandarin, and the 2016 annual conference featured a session with speakers from China, Taiwan, and Saudi Arabia.

AAHRPP has considerable reach and influence, both as a global accrediting body and as a resource for the research community. As such, AAHRPP is a frequent contributor at research-related events in the U.S. and overseas, including conferences in Canada, China, and India. AAHRPP also routinely offers webinars that tackle some of today's most complex research issues. Recent webinars have covered topics such as reportable events, vulnerable populations, patient-centered outcomes research, informed consent, and single IRB review of multisite studies. The organization's annual conference consistently provides the latest information on research trends and challenges. The 2016 conference, for example, included discussions on innovations in research design, biorepositories and the use of broad consent, and ethical issues in big data and genomic research.

In keeping with its emphasis on continuous improvement, AAHRPP also is taking a look at its own practices and has already begun implementing some

changes to realize the promise of what the organization refers to as “AAHRPP 2.0.” And more is on the way. One objective is to streamline the reaccreditation process, especially for organizations that have demonstrated their adherence to AAHRPP standards through at least two accreditation cycles: initial accreditation and first reaccreditation. The focus is on making reaccreditation less burdensome while maintaining the rigor and quality that have earned AAHRPP accreditation a place at the forefront of research protections.

That same rigor and quality will drive AAHRPP’s efforts and progress over the next 15 years and beyond. Working with partners old and new across the research community, AAHRPP will continue to evolve with and serve the research enterprise — anticipating challenges, driving solutions, and contributing to the global progress that is made possible by advancing safe, ethical research.

Conflict of Interest and Funding

No conflict of interest has been reported by the author.

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