

AAHRPP ADVANCE

One Standard Worldwide

SUMMER 2014

A Streamlined Process

In response to your input and in keeping with our commitment to continued quality improvement, AAHRPP has taken steps to streamline the accreditation process. The result is a process that's more flexible, transparent, and accessible—yet as rigorous as ever. [LEARN MORE](#)

International Inroads



AAHRPP standards are becoming the world's standards. Today, 20 organizations outside the U.S. have earned AAHRPP accreditation, giving us a presence in North America, Asia, Latin America, and the Middle East. [LEARN MORE](#)

PRIM&R: A Leader Among Leaders

Our series on AAHRPP's founding members continues with a look at Public Responsibility in Medicine and Research (PRIM&R), which spearheaded the creation of AAHRPP and enlisted the backing of other equally visionary organizations. [LEARN MORE](#)

Organizations Send Powerful Messages via AAHRPP Accreditation



For President and CEO Elyse I. Summers, J.D., AAHRPP's annual conference and quarterly Council on Accreditation meetings drive home both the breadth and the quality of the organizations that pledge to adopt AAHRPP's standards. Those that earn accreditation or reaccreditation also deliver compelling messages to the research community. [LEARN MORE](#)

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Latest Accreditations

- **New York State Department of Health**, Albany, New York
- **Sahyadri Hospital, Ltd.**, Pune, India
- **Tata Memorial Centre**, Mumbai, India

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2015 AAHRPP Conference
May 19-21 in Chicago



A Streamlined Process

Our goal is to continually improve the AAHRPP accreditation process by making it more flexible, transparent, and accessible—while maintaining its rigor. In keeping with that objective and in response to your input, AAHRPP has put the following changes into effect:

- **Simplified submissions:** Many documents can now be submitted on CD-ROM or USB flash drive, instead of as hard copy. Our long-term goal is to move to secure, online submissions.
- **Timeline at a glance:** This new, one-page planning tool outlines the accreditation process from start to finish.
- **Outreach to applicants early on:** A Step 1 reviewer will get in touch with your organization soon after you submit your application to help you identify areas that need to be addressed prior to a site visit.
- **Improved instructions:** “Instructions to Apply for Initial Accreditation and Reaccreditation” and “Instructions to Prepare a Response to the Draft Site Visit Report” have been edited for clarity and to help ensure a successful submission.
- **Streamlined reporting requirements:** AAHRPP no longer requests some previously required information that many organizations found difficult to obtain. Step 1, Step 2, and Annual Report documents have been updated to reflect these changes.

- **Switch from calendar to business days:** To eliminate confusion about due dates, deadline requirements define “days” as U.S. business days.
- **Additional time to prepare for site visits:** U.S. organizations now have 10 business days to gather documents for their site visit. International organizations have 40 business days to allow for translation.
- **Clarification of some AAHRPP standards:** AAHRPP is stepping up efforts to correct misconceptions about certain requirements and to emphasize the flexibility inherent in both the AAHRPP standards and government regulations. More information will follow in the weeks to come.
- **More consistent review process:** AAHRPP staff, Step 1 reviewers, site team leaders, and site visitors are working to improve consistency. AAHRPP will bring some operations back in-house to achieve this goal.
- **More detailed feedback forms:** New feedback forms capture more robust information from organizations and site visitors.

AAHRPP President and CEO Elyse I. Summers, J.D., discussed the changes during the annual conference in April, describing them as “changes to style, not substance. We believe that the AAHRPP accreditation process can operationalize an appropriate balance of ‘head and heart,’ ” she said. “We’ve been looking closely at practical things we can do to make the process better for all involved parties.”

New Accreditations Include NYS DOH and India’s National Comprehensive Cancer Center

AAHRPP recently accredited three more organizations, including one of the nation’s largest state health departments and India’s national comprehensive cancer center.

The newly accredited organizations are:

- **New York State Department of Health**, Albany, New York, including the Wadsworth Center for Laboratories and Research.
- **Sahyadri Hospital, Ltd.**, Pune, India, including Sahyadri Clinical Research & Development Centre, Sahyadri Speciality Hospital Deccan Gymkhana, Sahyadri Hospital Bopodi, Sahyadri Hospital Hadapsar, Sahyadri Hospital

Kothrud, Sahyadri Munot Hospital Swargate, and Sahyadri Speciality Hospital Nagar Road.

- **Tata Memorial Centre**, Mumbai, India, the national comprehensive center for cancer prevention, treatment, education, and research.

These accreditations reflect increasing acknowledgement, in the public and private sectors worldwide, that the AAHRPP gold seal is the mark of a quality human research program, where protecting participants is a shared responsibility—and a top priority.

International Inroads

AAHRPP has long recognized the global nature of the research enterprise and the importance of one standard for research protections worldwide. In 2006, just three years after AAHRPP's inaugural U.S. accreditations, Samsung Medical Center in Seoul, the Republic of Korea, made history by becoming the first international organization to earn the right to display the AAHRPP gold seal. Six months later, in March 2007, National Healthcare Group in Singapore followed suit.

Back then, international applications for accreditation were unusual. Today they are becoming the norm. In fact, during six of the past eight

AAHRPP Council on Accreditation meetings, international organizations were up for consideration. As a result:

- 20 organizations outside the U.S. have earned AAHRPP accreditation.
- AAHRPP has made inroads in critical international markets, including Asia, Latin America, and the Middle East.
- AAHRPP increasingly is being asked to participate in international conferences and to weigh in on global research issues. Earlier this year, for example, AAHRPP was among a select group invited

to participate in round-table sessions in India to discuss that country's plans for a national accreditation council. In the coming months, AAHRPP is planning to participate in conferences in China and Mexico and is co-sponsoring [a conference](#) in India.

AAHRPP's outreach has the potential to strengthen the research enterprise worldwide. As AAHRPP's standards become the world's standards, researchers, sponsors, and participants will all benefit from the resulting improvements in quality and protections.

PRIM&R: A Leader Among Leaders

This is the third in a series of articles on AAHRPP's Founding Members and the critical role they've played—and will continue to play—in AAHRPP's success.

All seven AAHRPP Founding Members deserve credit for their leadership and vision in creating an independent accrediting body to help strengthen research protections. Among these leaders, one organization—Public Responsibility in Medicine and Research (PRIM&R)—stands out.

It was the late 1990s, and the research enterprise was in the spotlight after several high-profile incidents. The federal government took strong steps, including the temporary shutdown of research programs, and there was talk of increasing regulatory oversight. PRIM&R came forward with an

alternative: Establish a voluntary, peer-driven accreditation model to help create an organizational culture of and commitment to protecting research participants.

Susan Kornetsky, M.P.H., Director, Clinical Research Compliance, Boston Children's Hospital, and Vice Chair, PRIM&R Board of Directors, remembers the early discussions about accreditation and subsequent efforts to draft preliminary accreditation standards.

"PRIM&R definitely was instrumental. We planted the seeds for accreditation and self-evaluation," she says.

Equally important, PRIM&R recognized the need to involve other organizations of stature as Founding Members. As a result, AAHRPP's founders hail from across the research enterprise and include some of its most

respected members: the Association of American Medical Colleges, Association of American Universities, Association of Public and Land-grant Universities, Consortium of Social Science Associations, Federation of American Societies for Experimental Biology, National Health Council, and PRIM&R.

From the beginning, the goal was for AAHRPP to become independent. The founders provided start-up loans, helped put a governance structure in place and, in the early years, held seats on AAHRPP's Board of Directors. In addition, PRIM&R was instrumental in developing the first set of AAHRPP's accreditation standards.

"We believed in AAHRPP and wanted to help lay the foundation," Ms. Kornetsky explains. "But it was always our intent, once AAHRPP was established, to move away and allow

it to flourish on its own. That's very much in keeping with PRIM&R's philosophy and with our reputation as neutral territory—a place where all research stakeholders can come together.”

Partners in fostering quality, bolstering protections

PRIM&R Executive Director Elisa A. Hurley, Ph.D., sees AAHRPP's and PRIM&R's missions and work as complementary with respect to maintaining a commitment to quality research and ethical practices. Although PRIM&R focuses on education, professional development, and policy, many of its educational programs relate to AAHRPP accreditation standards. In fact, organizations often turn to PRIM&R to help meet AAHRPP's requirement that accredited organizations provide education for those responsible for protecting the rights and welfare of research participants.

“PRIM&R has always been the go-to source for education,” Dr. Hurley says, “and that includes educating people about what accreditation is, what its benefits are, and how it relates to best practices.”

She credits AAHRPP and PRIM&R for playing key roles in one of the most significant gains in research protections: the shift to a comprehensive integrated approach that holds the entire organization accountable for protecting research participants.

“During those early discussions, there was a realization that it wasn't enough to focus just on the institutional review board,” Dr. Hurley says. “The decision was made to accredit entire institutions, not just IRBs, to reflect the belief that research protections are an institutional responsibility.

“And it worked,” she adds. “Today when we talk about the obligation to

protect human subjects of research, we talk about ‘human research protection programs, or HRPPs.’ It's part of the language.”

Dr. Hurley assumed the top post at PRIM&R in April, just months after Elyse I. Summers, J.D., became President and CEO at AAHRPP. Each is the second executive to head her respective organization. Both look forward to greater collaboration and shared successes. Recently, Dr. Hurley presented at AAHRPP's annual conference. This fall, PRIM&R's conference will include an AAHRPP pre-conference session on accreditation.

“It's an exciting time for both organizations. We've seen the passing of the torch from two founders,” Dr. Hurley says. “Elyse has long been involved with PRIM&R, so we have an excellent relationship. We're interested in exploring new ways to strengthen the ties between our organizations.”



SAVE THESE DATES

**2015 AAHRPP
Conference
May 19-21
Hilton Chicago**



AAHRPP
Association for the Accreditation of
Human Research Protection Programs, Inc.®

From the President and CEO

Sending powerful messages via AAHRPP Accreditation

As members of the research protection community, most of us are focused day in and day out on the countless details that together add up to strong, comprehensive safeguards for research participants. If we're lucky, we also get opportunities to take a step back, enjoy the big picture—and remember why we are dedicated to this line of work.

For me, two of those moments came during the June AAHRPP Council on Accreditation meeting and during our recent annual conference.

Those of you who are familiar with the AAHRPP process know that our Council on Accreditation meets four times a year to make decisions on accreditations and reaccreditations. I have attended three Council sessions since joining AAHRPP and, without exception, have been struck by both the breadth and the quality of the groups involved—and by the organizations' determination and enduring commitment to AAHRPP's rigorous standards.

At the June meeting, for example, the Council awarded accreditation to one of the largest departments of health in the U.S., to a hospital in India, and to that country's national comprehensive cancer center. The AAHRPP Council on Accreditation also reaccredited hospitals, universities, independent institutional review boards (IRBs), and other research organizations.

Every organization that earns AAHRPP accreditation or reaccreditation delivers these powerful messages to the rest of the research community:

- First and foremost, the organization is committed to safe, ethical research.
- The organization is in excellent company and adheres to the same research protection standards as some of the world's most respected institutions, including the National Institutes of Health.
- The organization is a trusted research partner, especially on studies involving other AAHRPP-accredited entities.

In today's global, collaborative research enterprise, such messages carry more weight than ever. Many organizations tell us that their AAHRPP accredited status is a determining factor in invitations to participate in multisite studies and other partnerships.



ELYSE I. SUMMERS, J.D.

This spring, I led my first AAHRPP conference where, quite frankly, I could not have been more impressed with my fellow attendees. About 400 turned out to hear their peers and other research leaders address topics including ethical issues in comparative research, data sharing and consent, managing multiple central IRBs, and more. We received excellent feedback about the quality of the conference sessions and presenters, as well as the networking opportunities. Our thanks to all of you who attended or participated in any way.

The conference also gave us a forum to officially welcome the newest members of the AAHRPP Board of Directors: Guy Chisolm, Ph.D., Former Director, Innovation Management and Conflict of Interest Program, The Cleveland Clinic (retired); Barbara Entwisle, Ph.D., Vice Chancellor for Research, University of North Carolina at Chapel Hill; Christopher States, Senior Environmental Planner (Biologist), California Department of Transportation; Ponni Subbiah, M.D., MPH, Founder, Global Med Strategies, LLC; and Edward Tucker, C.PA./A.B.V., Consultant, Ellin & Tucker, Chartered. We are indebted to them—and to all our Board and Council on Accreditation members, past and present—for their efforts on behalf of AAHRPP and those we have pledged to help protect.

Best regards,

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, J.D.
AAHRPP President and CEO