

AAHRPP ADVANCE

One Standard Worldwide

SPRING 2014

Accreditations Signal AAHRPP's Value, Influence

The accreditation of the National Institutes of Health and other key research players will have a ripple effect that will be felt around the globe. AAHRPP now has accredited organizations in North America, Latin America, Asia, and the Middle East. The list includes the world's largest public funder of research and largest private industry sponsor of clinical trials. SEE PAGE 2

Plenary: Comparative Effectiveness Research



The research protection community has a central role to play as the nation transitions to a "learning health system." Join us for a plenary session on this topic during our annual **conference** April 23-25. The session features Richard Platt, M.D., M.Sc., of Harvard Medical School, and Mark Schreiner, M.D., of the Children's Hospital of Philadelphia. SEE PAGE 3

Spotlight on Founding Member AAU

Our series on AAHRPP's founding members continues with a look at the Association of American Universities and its decision to recognize the importance of self-regulation in addressing research protection issues. SEE PAGE 5

Considering Accreditation? The Time Has Come



There has never been a better time to join the ranks of those who have earned the right to display the AAHRPP gold seal. AAHRPP President and CEO Elyse I. Summers, J.D., discusses why not-yet-accredited organizations should act now—and how AAHRPP can help. SEE PAGE 6

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Latest Accreditations

- **King Fahad Specialist Hospital-Dammam**, Dammam, Saudi Arabia
- **National Institutes of Health**, Bethesda, Md.
- **St. Jude Children's Research Hospital**, Memphis, Tenn.
- **Taipei Medical University Hospital**, Taipei, Taiwan

Of Note

- **Check Out Our 2014 Webinars**

Latest Accreditations Signal AAHRPP's Value, Influence

NIH, first hospital in the Middle East, second Taiwan organization, and St. Jude now accredited

Every accreditation is significant because it extends AAHRPP's high standards and increases protections to more research participants. But some accreditations create a larger ripple effect—one that is felt throughout the global research enterprise.

That was the case in March, when the National Institutes of Health (NIH), King Fahad Specialist Hospital-Damman (KFSH-D) of Saudi Arabia, Taipei Medical University Hospital of Taiwan (TMUH), and St. Jude Children's Research Hospital all earned AAHRPP accreditation.

Separately, each is impressive: the world's premier research organization, the first organization in the Middle East to earn AAHRPP accreditation, a highly ranked university-affiliated hospital in Taiwan, and a world-renowned children's research hospital. Together, these institutions provide the strongest evidence to date that AAHRPP's accreditation standards are becoming the standards of choice around the globe.

"These latest accreditations leave no doubt that AAHRPP plays a singular role in helping to protect research participants worldwide," AAHRPP President and CEO Elyse I. Summers says. "The most respected and influential organizations in virtually every sector of the research enterprise—including government, academia, children's research, and private industry—have

committed to AAHRPP standards. Many more are in the pipeline."

To date, AAHRPP has accredited:

- Organizations in 46 states, Canada, China, India, Mexico, the Republic of Korea, Saudi Arabia, Singapore, and Taiwan
- All major U.S. independent institutional review boards (IRBs)
- NIH and the National Cancer Institute (NCI) Central IRB
- Pfizer, Inc., the largest industry sponsor of clinical research

In addition, more than 60 percent of U.S. research-intensive universities and over 65 percent of U.S. medical schools are either AAHRPP accredited or have begun the accreditation process.

NIH: A Global Leader

NIH's AAHRPP accreditation covers the intramural research program, including investigators at more than 20 institutes and centers on all NIH campuses. These investigators conduct more than 1,000 clinical studies every year. Participants now have the added assurance of knowing these studies are run in accordance with AAHRPP's exacting standards for quality and research protections.

Equally important is NIH's standing in the global research community, which historically has looked to NIH to set the example—in part, because of its role as the world's largest public funder of research.

"NIH is the world's premier research organization. NIH has been at the forefront of research innovation and ethics for decades, and organiza-

tions the world round follow NIH's lead," Ms. Summers says. "The decision to seek AAHRPP accreditation delivers a powerful message to research institutions about NIH's commitment to research protections and the value of AAHRPP's standards."

Impressive Expansion Overseas

With its accreditation of KFSH-D and TMUH, AAHRPP continues to expand its influence overseas and demonstrates, once again, that AAHRPP standards have universal application. Both hospitals were accredited in accordance with the laws of their own nations, AAHRPP standards, and U.S. regulations. KFSH-D also was accredited under ICH-GCP (E6) guidelines.

"These accreditations in Saudi Arabia and Taiwan are a reminder that we truly can have one standard for research protections worldwide," Ms. Summers says. "That standard has been set by AAHRPP."

KFSH-D's decision to pursue AAHRPP accreditation is the latest example of the hospital's emphasis on continuous quality improvement. KFSH-D was the first Saudi Ministry of Health facility to earn Joint Commission International (JCI) accreditation. The hospital's Research Administration was established in 2010, and from the beginning, KFSH-D pledged to develop the infrastructure required to meet AAHRPP standards and GCP guidelines.

TMUH is accredited by JCI and by the Forum for Ethical Review

Latest Accreditations Signal AAHRPP's Value, Influence

Committees in the Asian and Western Pacific Region. The hospital serves as the research base for Taipei Medical University and has earned a reputation as a leader in cancer and telehealth research.

A Household Name in Children's Research

St. Jude joins 11 other U.S. children's hospitals, coast to coast, in earning AAHRPP accreditation—and extends AAHRPP's protections to the thousands of children from around the globe who turn to St. Jude each year.

St. Jude creates more clinical trials for cancer than any other children's

hospital worldwide and enrolls more than 90 percent of its pediatric cancer patients in research studies. The hospital is the national coordinating center for the Pediatric Brain Tumor Consortium and the Childhood Cancer Survivor Study, both funded by NCI. St. Jude also is the coordinating center for an NIH-funded national study of sickle cell disease.

“The name St. Jude has long been synonymous with quality research, especially in the area of children's cancer,” Ms. Summers said. “AAHRPP accreditation is yet another indication of St. Jude's unwavering commitment to some of the world's most vulnerable patients and research participants.”

Plenary: Comparative Effectiveness Research

Register now for April 23-25 Conference in Utah



Come learn more in Utah

As the nation transitions to a “learning health system,” the research protection community has a central role to play in decisions on incorporating effectiveness research at the point of care.

That's one of the messages that Richard Platt, M.D., M.Sc., will deliver during a plenary session, “Ethical Issues in Comparative Effectiveness Research,” on April 25 at the **2014 AAHRPP conference**. Dr. Platt chairs the Harvard Medical School Department of Population Medicine at the Harvard Pilgrim Health Care Institute in Boston, and leads the coordinating center of the Patient-Centered Outcome Research Institute's (PCORI's) National Patient-Centered Research Network (PCORnet). This developing

national resource for comparative effectiveness research includes 29 research networks.

The plenary session also features Mark Schreiner, M.D., of The Children's Hospital of Philadelphia (CHOP). Dr. Schreiner is Associate Professor of Anesthesiology and Critical Care and Associate Professor of Pediatrics at the Perelman School of Medicine at the University of Pennsylvania. He also serves as the chair of CHOP's Committees for the Protection of Human Subjects.

Dr. Platt cites increasing recognition of the need to integrate comparative research and health care delivery to gather evidence on which treatment

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methods work best for whom. At the same time, he acknowledges both short- and long-term concerns about moving to a learning health system.

“Most of us agree that we should be learning from the care we deliver, but that changes the way we’ve also thought about research as quite separate from the delivery of care,” Dr. Platt says. “We need to be thoughtful about how learning (research) activities should dovetail with those in the normal care setting.

“This raises a series of new questions about ensuring that we have the right kind of oversight of learning activities embedded in the health care setting,” he adds. “The AAHRPP conference audience is the ideal group to engage in this conversation—both about how

we interpret and implement current regulations and what changes we should consider moving forward.”

The April 25 plenary session is one of four at the 2014 AAHRPP Conference: Quality Human Research Protections. The theme of the three-day gathering is “Leading the Way: From the Essentials to the Cutting Edge.”

The other plenary sessions follow:

- “Building Quality into All Aspects of Human Research Protection,” presented by Briggs Morrison, M.D., Astra Zeneca
- “Reporting Results and Incidental Findings to Research Participants,” featuring Jeffrey Botkin, M.D., the University of Utah
- “Groundbreaking Clinical Research and Human Research Protections

Go Hand in Hand,” with Lynnette Nieman, M.D., National Institutes of Health

The conference’s more than 30 sessions explore data sharing and consent, ethical challenges presented by Internet research, managing multiple central institutional review boards, and organizational conflict of interest, among other subjects.

Poster presentations will highlight innovative solutions and best practices. Pre-conference workshops will cover topics geared toward organizations that are interested in pursuing AAHRPP accreditation or are in the midst of the accreditation process. For details, see the conference **agenda**.

2014 AAHRPP Conference



QUALITY HUMAN
RESEARCH
PROTECTION
PROGRAMS



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

Spotlight on Founding Member AAU

This is the second 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.

When the Association of American Universities (AAU) agreed in 2001 to help create an independent accrediting body for human research protection programs, the decision underscored both the need for improvements in protections and the research community's determination to police itself.

"It was unusual for AAU to be involved in AAHRPP's founding because our efforts more typically focus on alleviating the cumulative burden of research regulations," says Carrie Wolinetz, Ph.D., Associate Vice President for Federal Relations at AAU. "Instead, we were helping to create something that would result in new requirements: voluntary ones, but requirements nonetheless.

"Our involvement, and that of the other six founding organizations, indicates just how strongly we felt about the need for human subjects research to be of the highest quality," she adds.

At the time, the research community had been rocked by a series of widely publicized incidents, some of which resulted in government shutdowns of research programs. Seven national organizations—AAU, the Association of American Medical Colleges, the Association of Public and Land-grant Universities, the Consortium of Social Science Associations, the Federation of

American Societies for Experimental Biology, the National Health Council, and Public Responsibility in Medicine and Research—decided to tackle these issues head-on.

Together, the groups established AAHRPP. The new, independent organization developed an objective, peer-reviewed accreditation process, built on rigorous standards and recognition of the need to advance research and benefit from its findings.

"In the early years, both research universities and AAHRPP struggled to find the balance between setting appropriately high research standards and not creating obstacles to research progress," Dr. Wolinetz notes. "It has been an evolving relationship and one which continues to make positive progress." In the years since its founding, AAHRPP has emerged as a global leader and an advocate working on behalf of research participants and continuous improvements in research quality.

"For the research community, AAHRPP and AAHRPP accreditation demonstrate to the world that we are doing everything in our power to be good stewards of human subjects research and of the taxpayer dollars that fund this research," Dr. Wolinetz says. "Through AAHRPP accreditation we are holding our organizations to the highest possible standards for quality, ethics, and adherence to regulatory requirements."

Applauding AAHRPP's independence

As AAHRPP has come into its own, the relationship between AAHRPP and AAU has evolved accordingly. "That's as it should be," Dr. Wolinetz says, especially since many of the organizations seeking AAHRPP accreditation are AAU members.

AAU represents 62 leading research universities in the U.S. and Canada. The association educates policymakers about the importance of investing in research and ensures that AAU members have a voice in determining new approaches to research and protections.

AAU members are among the most influential when it comes to teaching the next generation of researchers, grounding them in responsible conduct, and preparing them for the challenges of the global research community.

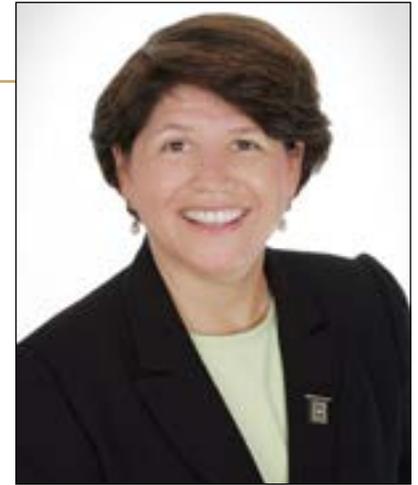
Accreditation and the emphasis on one set of standards worldwide give AAHRPP a supportive role in research education. At AAHRPP-accredited institutions, all faculty and students conduct research involving human participants in accordance with AAHRPP standards.

"For universities, medical schools, research institutions, and others involved in global research, having that AAHRPP gold standard to point to really does make a difference," Dr. Wolinetz says. "AAHRPP is the expert, and we will always support and be connected to them."

From the President and CEO

If you've been considering AAHRPP accreditation, the time has come

AAHRPP's most recent accreditations—of the National Institutes of Health (NIH), our first organization in the Middle East, St. Jude Children's Research Hospital, and our second organization in Taiwan—deliver an unequivocal message to those engaged in research involving human participants. If you're serious about quality, it's time to pursue AAHRPP accreditation.



ELYSE I. SUMMERS, J.D.

Since our founding, AAHRPP has been steadily making inroads across the U.S. and, more recently, around the globe. As a result, AAHRPP accreditation is now the mark of quality for human research protection programs (HRPPs) in North America, Latin America, Asia, and the Middle East. Equally important, the value of AAHRPP accreditation is recognized by both the world's largest public funder of research and the world's largest industry sponsor of clinical trials. (Pfizer, Inc. earned AAHRPP accreditation last year.)

Our continued progress is great news for organizations that already are AAHRPP accredited, especially given today's increasing emphasis on collaboration. Your AAHRPP accreditation signals that you are a preferred partner. You've demonstrated your commitment to quality and to protecting research participants. And you can be trusted to adhere to the same standards as NIH and other AAHRPP-accredited organizations.

What if you're not yet AAHRPP accredited? Then you have an incredible opportunity.

There has never been a better time to join those who have earned the right to display the AAHRPP seal. Most organizations within the research enterprise will acknowledge that becoming AAHRPP accredited has always been a **good thing** to do. But some questioned whether it was the **smart thing**. At one time, there was an element of risk. What if AAHRPP accreditation did not take hold and you invested time and resources that could be better spent elsewhere?

Now that question has been answered decisively. AAHRPP accreditation will not only strengthen your HRPP but will also bolster your competitive standing. AAHRPP-accredited organizations join the ranks of those whose accreditation status identifies them as smart choices to potential funders and collaborators. These organizations don't just "talk the talk." They "walk the walk."

Organizations thinking about seeking AAHRPP accreditation can also count on AAHRPP for critical support throughout the process.

If you and your organization are willing to dedicate yourselves to AAHRPP accreditation, we will do everything possible to help you meet AAHRPP standards and achieve that goal. I'll start by inviting you to our upcoming conference, which includes a full day of pre-conference workshops focused exclusively on how to apply and prepare for AAHRPP accreditation. I hope to see you there. Even more, I look forward to congratulating you in the not-too-distant future on joining the ranks of the AAHRPP accredited.

Best regards,

A handwritten signature in blue ink that reads "Elyse I. Summers". The signature is fluid and cursive, with a long horizontal flourish extending to the right.

Elyse I. Summers
AAHRPP President and CEO