AAHRPP ADVANCE
Enhancing Protection for Research Participants

FALL 2013

Introducing AAHRPP's New CEO

AAHRPP President and CEO Elyse I. Summers, J.D., begins her tenure by sharing some of her views on the role of AAHRPP accreditation, her vision for AAHRPP, and the challenges facing the global research enterprise. Expect an emphasis on continued growth, quality, and increased collaboration. SEE PAGE 2

Making Inroads in Another Emerging Market

Latin America is fast becoming a preferred market for clinical trials. Rapid growth has been accompanied by concerns about the quality of research and the strength of research protections. In anticipation, as it has in other emerging markets, AAHRPP has been reaching out to Latin American organizations—with success. SEE PAGE 4

Genomic Research: Taking Steps to Secure Data

As researchers gain unprecedented access to GWAS datasets, IRBs grapple with finding a balance between advancing science and ensuring the confidentiality of individual participant data. AAHRPP recently hosted two webinars to offer guidance on this issue and, in response to unusually high demand, provides some highlights. SEE PAGE 5

Conference Registration Begins November 1

The 2014 AAHRPP Conference: Quality Human Research Protection Programs will focus on "Leading the Way: From the Essentials to the Cutting Edge." The **conference** will be held April 23-25 in Salt Lake City, Utah. Online registration begins November 1.

FALL 2013

IN THIS ISSUE

Newly Accredited Organizations

- **Ann & Robert H. Lurie Children's Hospital of Chicago**, Chicago, IL
- **Columbia Medical Center of Plano**, Plano, TX
- **Kyung Hee University Hospital**, Seoul, South Korea
- **Mississippi State University of Agriculture and Applied Science**, Mississippi State, MS

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Introducing Elyse I. Summers, J.D., AAHRPP President and CEO

ELYSE I. SUMMERS, J.D.

On October 14, Elyse I. Summers, J.D., took the helm at AAHRPP as President and CEO. Ms. Summers brings almost 15 years of experience in research protections, most recently as Director, Division of Education and Development, at the Office for Human Research Protections (OHRP). She has held positions with the Food and Drug Administration and Association of American Universities (AAU). As an attorney, Ms. Summers has practiced the law of tax-exempt organizations and advised clients on federal regulations and ethical issues related to conducting biomedical research and to the drug approval process.

In the following interview, Ms. Summers shares some of her views on the role of AAHRPP accreditation, her vision for AAHRPP, and the challenges facing the global research enterprise.

Q: What is the role of AAHRPP accreditation? Has it been effective?

A: To me, any discussion of AAHRPP accreditation begins with ethical principles, such as those expressed in the Declaration of Helsinki and the Belmont Report. These documents provide the philosophical basis of the research protections that we uphold every day. The regulations that emerged from these foundational documents delegate enormous authority and responsibility to research organizations to carry out the regulatory mandate. AAHRPP can be instrumental in helping organizations fulfill that responsibility. AAHRPP accreditation is a logical, robust, and elegant manifestation of an organization's commitment to, and ownership of, these fundamental ethical principles.

As for AAHRPP's effectiveness, one need only look at the metrics that AAHRPP collects and analyzes. The data show increased efficiencies in the time it takes for protocols to be reviewed and approved. A more efficient, manageable institutional review board (IRB) process advances research and, as a collateral benefit, helps organizations attract and retain high-caliber researchers. AAHRPP accreditation is fast becoming the norm for high-quality research programs around the globe. AAHRPP accreditation is the gold seal and the signal that an organization has committed to a very high level of protections for research participants. Increasingly, researchers and participants alike feel more comfortable working with an organization if it has attained AAHRPP accreditation.

Q: What do you see as AAHRPP's primary roles in the research enterprise?

A: During my almost 15 years in the field of research protections, there's been an increase in the desire and commitment of organizations to improve their human research protection programs (HRPPs). With that has come a concomitant investment in the resources necessary to bring that commitment to the fore. AAHRPP has been instrumental in supporting and helping to fuel these trends.

AAHRPP's primary role is to provide the research community with an accessible but rigorous process for ensuring adequate protection of the human volunteers who make the entire human research enterprise possible. AAHRPP has become synonymous with quality and leadership in human research protections. It will be my job to build on AAHRPP's reputation as the indispensable leader in the accreditation of HRPPs, and to bring a laser-like focus on maintaining and elevating the high quality of HRPPs, both in the U.S. and around the world.

Another of my priorities will be for AAHRPP to play a leading, complementary role as a trusted repository of accurate, helpful information. I see AAHRPP as an invaluable resource—a source of support and encouragement to organizations seeking to strengthen their HRPPs.

CONTINUED PAGE 3

Q: Looking ahead, what is your vision for AAHRPP?

A: I envision what I like to think of as AAHRPP 2.0, ready to help advance the research enterprise well into the 21st century. There is broad recognition across the research community that quality and sophistication matter; I've seen it throughout my tenure at OHRP. Earlier this year, for instance, I was speaking at a conference in Michigan, and representatives from a small, lesser known college approached me. They were interested in establishing their IRB in full compliance with the regulations, in part, to position themselves to collaborate with larger, top-tier organizations. Whether they have a biomedical or behavioral bent, smaller colleges and universities really want to partner with well-known organizations. The same can be said of smaller community hospitals and major academic medical centers. AAHRPP accreditation can help facilitate that collaboration.

It follows, then, that one of my goals domestically is for AAHRPP to make significant inroads among smaller colleges and universities, community hospitals, and other smaller organizations that are trying to be compliant and to take their HRPPs up to the next level.

Another goal of mine is to re-energize AAHRPP's historic ties with its founding members: the 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, Public Responsibility in Medicine and Research, and AAU (where, incidentally, I began my professional career). I plan to reach out to these and other organizations. In an increasingly complex and challenging research environment, it makes sense for AAHRPP to leverage these long-standing relationships to foster collaboration and increase support for AAHRPP accreditation.

On the international front, many organizations are interested in demonstrating to the world that they are committed to doing right by human participants. And, of course, the same holds true for commercial entities, whether here or abroad. AAHRPP accreditation can help these organizations strengthen their research protections and their standing in the research enterprise.

"In an increasingly complex and challenging research environment, it makes sense for AAHRPP to leverage long-standing relationships to foster collaboration and increase support for AAHRPP accreditation."

Q: What are some of the most pressing challenges facing today's research enterprise?

A: One of the major challenges is the same as that faced by almost every other enterprise: to do more with less. We see that in organizations of every size and in every sector, from academic research centers to small colleges, community hospitals, and even the pharmaceutical industry. This is a case where AAHRPP accreditation and the resulting efficiencies add considerable value. AAHRPP accreditation can help organizations be competitive and conduct high-quality research.

Another challenge comes with the increasing and reasonable desire for greater collaboration and joint IRB review of multisite research studies. Here, again, AAHRPP accreditation has a role to play. As an objective indicator of quality, AAHRPP accreditation offers assurances that can raise the comfort level among research partners and ultimately result in increased multisite collaboration.

AAHRPP Extends Influence to Latin America

Latin America is fast becoming a preferred market for clinical trials. According to an Office of Inspector General (OIG) analysis, in fiscal year 2008, Latin America accounted for 26 percent of research participants in studies cited in marketing applications approved by the Food and Drug Administration (FDA). Industry experts expect that percentage to increase significantly in coming years as language and cultural barriers are overcome.

Rapid growth often brings concerns about the quality of research and the strength of research protections. In anticipation, as it has in other emerging markets, AAHRPP has been reaching out to Latin American organizations, encouraging them to make a commitment to uphold AAHRPP accreditation and its high standards.

Those efforts have begun to bear fruit. In June, AAHRPP accredited its first organization in Latin America, Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubirán in Mexico City. Organizations in other Latin American countries have begun the AAHRPP-accreditation process.

The research landscape

Much of Latin America's appeal is based on recruitment potential. The region's more than 500 million residents include a sizable treatment-naive population, clustered in major urban areas. As a result, average enrollment at Latin American clinical trial sites is more than triple that of sites in other regions. Because enrollment in a clinical trial often offers access to treatment that otherwise would be unavailable, retention rates also tend to be high.

The prevalence of historically Western diseases—such as arthritis, cancer, and heart disease—is another attraction, as is the opportunity to tap a racially and ethnically diverse population. Other pluses include advances in healthcare regulations, increased adherence to International Conference on Harmonisation–Good Clinical Practice standards, proximity to the United States, and similar North and Latin American time zones.

Yet barriers exist. Although Latin America has only two official languages, there are considerable linguistic variations by region. These must be taken into account when translating documents and obtaining informed consent. Even when documents are translated accurately, in areas with high illiteracy rates compliance can suffer if participants have trouble understanding written instructions.

Oversight remains an issue, in part because FDA resources have not kept pace with the growth of foreign clinical trials. The OIG report "Challenges to FDA's Ability to Monitor and Inspect Foreign Clinical Trials" notes that for applications approved in 2008, FDA inspected only 0.7 percent of overseas clinical trial sites.

The role of AAHRPP accreditation

AAHRPP was quick to recognize the increasingly global nature of the research enterprise and the role that AAHRPP accreditation can play in moving toward one standard worldwide for research protections. Just five years after its founding, with the accreditation of Samsung Medical Center in Seoul, South Korea, in 2006, AAHRPP began extending its influence—and its emphasis on comprehensive research protections—to key emerging markets.

Since then, AAHRPP has accredited additional organizations in Korea and has made inroads in India, China, and, more recently, Latin America. AAHRPP's progress around the globe has repercussions abroad and in the U.S. When international organizations pledge to adhere to AAHRPP's high standards, research participants benefit from safer practices. And patients worldwide can have more confidence in the quality of the research, the accuracy of the data, and the efficacy of the resulting medical treatments.

Genomic Research: Addressing the Risks of Unprecedented Database Access

Technological advances have added to both the promise of genomic research and the potential issues to consider when reviewing the research. The tools that help make databases of unprecedented scale available to researchers can increase the risk to participants by potentially compromising the confidentiality of individual participant data. The challenge is to strike a balance between moving science forward and respecting participants. And the responsibility for achieving that balance often rests with the institutional review board (IRB).

Many human research protection programs (HRPPs), especially those whose organizations participate in National Institutes of Health (NIH) genome-wide association studies (GWAS), already have policies that address the special nature of genomic-related research, in accordance with NIH guidance. Even so—as two recent, oversubscribed AAHRPP webinars attest—there is significant demand for more information.

For those who could not participate in the AAHRPP webinars, this article highlights key points made during those presentations. It also discusses the approach adopted by Fred Hutchinson Cancer Research Center (FHCRC), provides resources for IRBs that are drafting or updating genomic research policies, and includes this **link** for those who wish to comment on the draft NIH Genomic Data Sharing Policy. **The deadline to submit comments is November 20.**

Webinar highlights

Featured presenter was Laura Lyman Rodriguez, Ph.D., Acting Chief of the Genomic Healthcare Branch and Director of the Division of Policy, Communications, and Education at the NIH National Human Genome Research Institute. Dr. Rodriguez was instrumental in developing the policy for sharing NIH-supported genomic research data. Central to that policy is the fundamental belief that "the greatest public benefit will be realized if data from genomic studies are made available under terms and conditions consistent with the informed consent provided by individual participants … ."

For genomic research in today's laboratory or clinic, the consent process should include a discussion of the following:

- Storage and sharing of data, including the likelihood that researchers will continue to have access to participants' data for a lengthy, and possibly unlimited period of time.
- Potential for breaches of confidentiality, especially as technological advances make it easier to connect de-identified information to participants.
- Whether there will be disclosure of health information and incidental findings to participants and their family members.
- Risks to participants and relatives if data become publicly available to entities not covered by the Genetic Information Nondiscrimination Act.
- Provisions for returning samples or removing participant information from the database.

Even the most comprehensive discussions might not be able to assuage participants' concerns. However, studies show that trust and willingness to participate are linked to perceptions of autonomy and respect. "The key is transparency," Dr. Rodriguez said.

One organization's approach

At FHCRC (AAHRPP accredited since March 2008), policies and consent documents have evolved in recent years to reflect NIH guidance and concerns about protecting genomic data. FHCRC has a separate policy for IRB review of GWAS and requires researchers to complete a GWAS submission supplement for studies if FHCRC will be uploading resulting data to central repositories.

The six-page supplement requests information about researchers' plans to de-identify the data set and takes researchers step by step through a series of questions designed to assess the scope of consent granted by participants, as well as their understanding of the risks of taking part in the research.

Consent-related questions address the issues raised by NIH in its "points to consider" when reviewing data submission plans, including potential benefits, risks, return of research results, privacy and confidentiality protections,

CONTINUED PAGE 6

withdrawal of consent, and commercial use. The FHCRC supplement also tackles one of the more complicated issues: Can data collected years ago be used in current and future research?

In some cases, the answer can be found in prior consent forms that specifically allow or preclude future uses—and researchers cite those forms to help the IRB make its determinations. The answer is less clear for studies that were undertaken decades ago, when data sharing was not common and, therefore, not addressed.

"The IRB's review of each proposed GWAS submission is taken seriously, and our GWAS supplement reflects that," said Karen Hansen, Director, FHCRC Institutional Review Office. "We designed the supplement specifically to support IRB committee members as they consider whether to approve, approve with restrictions, or disapprove the submission of data to an NIH GWAS repository. In more complex cases, the supplemental information often proves invaluable in making the best determination."

Resources for IRBs

To help HRPPs develop GWAS submission policies and documents, FHCRC has offered to share its IRB **policy** and GWAS supplement. For the supplement, click on this **link**, scroll down to "Less commonly used supplements," and download the PDF for "GWAS Submission Supplement." NIH resources include:

GWAS: Institutions and IRBs
GWAS: NIH Points to Consider
National Human Genome Research Institute: Informed Consent for Genomics Research
Draft NIH Genomic Data Sharing Policy Request for Public Comments

AAHRPP Conference Registration begins November 1

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