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FALL 2016

AAHRPP-Accredited Schulman IRB Selected for Cancer MoonShot 2020

Schulman IRB has been named the national IRB of record for Cancer MoonShot 2020, an ambitious, comprehensive effort to accelerate next-generation immunotherapy and, ultimately, win the war on cancer. Cancer MoonShot 2020 officials say AAHRPP accreditation was a prerequisite. **LEARN MORE**

Informed Consent: Assessing and Enhancing the Conversation

The National Institute of Mental Health Intramural Research Programs is observing new investigators and using a training and assessment tool to evaluate informed consent discussions for content and communication style. The goal is to fulfill the ethical and regulatory requirements for informed consent—*and* improve the experience for prospective research participants. **LEARN MORE**

Introducing AAHRPP's International Site Visitors

We have assembled a team of highly qualified site visitors who will specialize in conducting reviews outside the U.S. As with all our site visitors, the international team members were selected for their expertise in human research protections and their first-hand experience in meeting AAHRPP's accreditation standards. **LEARN MORE**

Helping You Transition to Single IRB Review

AAHRPP President and CEO Elyse I. Summers, JD, shares information on our new work group, created to anticipate and address some of the challenges research organizations can expect as we move to single IRB review for multisite studies. The group is just the latest example of AAHRPP's role as a resource for research organizations. **LEARN MORE**

Upcoming Webinars

- **October 25 and 27:** Measuring the Quality and Process of Informed Consent

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FALL 2016 INSIDE

Latest Accreditations

- **Apollo Hospitals Enterprise Ltd.,** Chennai, Tamil Nadu, India. Includes the following:
  - Apollo Hospitals International Ltd., Ahmedabad
  - Apollo Hospitals, Chennai
  - Apollo Health City, Hyderabad
  - Apollo Specialty Hospitals, Madurai
  - Indraprastha Apollo Hospital, New Delhi
- **CAMC Health Education and Research Institute, Inc.,** Charleston, West Virginia
- **University of Nebraska Medical Center,** Omaha, Nebraska

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

Schulman Named IRB of Record for Cancer MoonShot 2020

AAHRPP accreditation was prerequisite

Schulman IRB (AAHRPP accredited since June 2008) has been named the national IRB of record for Cancer MoonShot 2020, an ambitious, comprehensive effort to accelerate next-generation immunotherapy and, ultimately, transform cancer treatment.

Schulman will provide review services for Cancer MoonShot 2020's Quantum Integrative Lifelong Trial (QUILT) program, which is expected to enroll up to 20,000 participants in clinical trials over the next three years. The trials will test multiple combinations of therapies on patients who have undergone whole genome (DNA), transcriptome (RNA), and quantitative proteomic analyses.

"The QUILT program stands to remove one of the most significant barriers to winning the war on cancer—namely, the research of new cancer treatments in 'silos' across industry and academia," says Schulman IRB President and CEO Michael Woods. "While immunotherapies hold great promise for treating cancer, they must be researched not for their effectiveness alone but in combination with other treatments. The QUILT program promises to do just that, and we are proud to be a part of this ambitious and critical initiative."

> **"AAHRPP accreditation was one of the principal requirements for IRB selection. . . If an organization is AAHRPP accredited, we can be confident that they comply with the federal regulations."**
>
> *—Chris Beardmore, TRM/NantWorks*

Cancer MoonShot 2020 is separate from the National Cancer MoonShot announced earlier this year by President Barack Obama. Primarily a private sector effort, Cancer MoonShot 2020 is led by Patrick Soon-Shiong, MD, founder and CEO of NantWorks. The focus is on investing in combination immunotherapy as the next standard of care, with a goal of developing an effective vaccine-based immunotherapy to combat cancer by 2020.

Schulman was chosen for its combination of AAHRPP accreditation, oncology expertise, and reputation for technological innovation and collaboration. The independent IRB has since announced that it is expanding oncology services and has added Michele Russell-Einhorn, JD, former senior director of Dana-Farber Cancer Institute's Office for Human Research Studies, to the Schulman team. Ms. Russell-Einhorn also serves as co-chair of the Subpart A Subcommittee of the U.S. Department of Health and Human Services Secretary's Advisory Committee on Human Research Protections and as an AAHRPP site visitor.

"AAHRPP accreditation was one of the principal requirements for IRB selection," says Chris Beardmore, President of Translational Research Management (TRM). A site management organization that is part of the NantWorks family of companies, TRM played a key role in choosing the IRB of record. "AAHRPP has essentially become a credentialing and standards organization," he says. "If an organization is AAHRPP accredited, we can be confident that they comply with the federal regulations."

Mr. Beardmore also cites Schulman's innovative use of technology to streamline submissions, enable electronic informed consent, and manage and present data more effectively. The ability to assemble, mine, manage, and secure data will be essential to Cancer MoonShot 2020's success.

Equally important is the IRB's approach to a challenge and initiative of such magnitude. "This is not a case in which all the answers already exist," Mr. Beardmore says. "We need a partner that helps us work through complex medical and ethical issues to ensure the protection of the rights and welfare of patients who consent to participate in this important effort. Schulman has made that commitment."

As such, Schulman IRB could take a place in the vanguard of both advances in cancer treatment and the evolution of the role played by IRBs.

A major goal of Cancer MoonShot 2020 is to be able to use precision medicine to fight cancer—to develop patient-specific vaccines that treat and prevent the recurrence of the disease. "At that point, we might have sufficient data to say, 'The traditional standard of care is not in the best interest of this patient,'" Mr. Beardmore explains. "Ethical decisions might need to be made, and the IRB will be at the forefront of those decisions."

Informed Consent: Assessing and Enhancing the Conversation

The informed consent process has long presented challenges for research organizations. Among the key concerns is whether prospective research participants understand the information they receive and are comfortable asking questions.

A pilot program at the National Institute of Mental Health Intramural Research Programs (NIMH IRP) tackles these concerns by observing new investigators and using a training and assessment tool to evaluate informed consent discussions for both content and communication style. The goal is to lay the foundation for clear, comfortable, and engaging conversations that can fulfill the ethical and regulatory requirements for informed consent—*and* improve the experience for prospective research participants at the same time.

The assessment tool covers all content included in the Office for Human Research Protections checklist for informed consent. What sets the tool apart is that it also emphasizes the importance of professionalism, communication skills, and presentation style.

"Contextual and environmental factors can really affect the research participant's experience of the informed consent process," says Mary Ellen Cadman, RN, MSN, MSW, LCSW-C, Clinical Research Advocate in the Human Subjects Protection Unit, NIMH IRP. "Body language, eye contact, allowing enough time for discussion—these variables are just as important as the content elements of informed consent."

Ms. Cadman will discuss this approach to informed consent on October 25 and 27 during **AAHRPP webinars** on "Measuring the Quality and Process of Informed Consent." AAHRPP addresses the informed consent process in Standard III-1, Element III.1.F. (below).

Informed Consent Process

AAHRPP Element III.1.F

Researchers employ consent processes and methods of documentation appropriate to the type of research and the study population, emphasizing the importance of comprehension and voluntary participation to foster informed decision-making by participants.

Rooted in experience and observation

The NIMH IRP assessment tool reflects extensive experience monitoring informed consent discussions between investigators and research participants. Because some mental health patients may be vulnerable, a clinical research advocate is present at every informed consent conversation with participants in NIMH inpatient studies. An advocate is also present for informed consent discussions with subjects enrolled in outpatient studies that have been determined by the IRB to include vulnerable subjects or those at more than minimal risk.

"We have observed almost 4,500 informed consent discussions and have seen so many styles of delivery for this vital information—some really good and some with room for improvement," Ms. Cadman explains. "We realized we could draw on this experience to develop a tool that provides an extra level of protection for research participants and for new fellows engaged in obtaining informed consent."

Ms. Cadman will review the tool during the upcoming AAHRPP webinars, in part to encourage attendees to consider developing similar training and assessment vehicles. Food and Drug Administration and Department of Health and Human Services regulations authorize the IRB or a third party to observe the consent process. Yet few IRBs exercise this authority.

"NIMH's experience demonstrates the value of using observation as a learning and feedback tool," says Sarah Kiskaddon, JD, MA, AAHRPP Vice President, Global Development and Public Affairs. "The NIMH approach correctly places more emphasis on the consent process, which AAHRPP supports."

Under the NIMH pilot program, at the request of Clinical Director Maryland Pao, MD, all new NIMH fellows are observed and evaluated during their first informed consent discussion. "That top-down support has been critical to the success of the program," Ms. Cadman says. "It sends a clear message that our clinical director supports this additional training and the resulting enhanced protections for research participants."

When informed consent discussions are conducted in an empathetic way, participants tend to feel more secure in their understanding of the study and the decision they've made. Investigators benefit as well because they can be confident that those who agree to participate have truly given their consent.

A comfortable, conversational approach can also foster rapport between investigator and participant. "That initial meeting between patient and doctor, or subject and investigator, is a very important moment in their relationship," Ms. Cadman adds. "Equipping investigators to do a better job during this first meeting can help establish that critical subject-researcher partnership."

Meet Our International Site Visitors

In recent years, AAHRPP has made considerable progress toward achieving our goal of "one standard worldwide." Today, 36 AAHRPP-accredited organizations, or about 16 percent, are located outside the U.S. Most are based in Asia.

To reflect this increased diversity and to better meet the needs of international organizations, AAHRPP has assembled a team of highly qualified site visitors who will specialize in conducting reviews outside the U.S. As with all our site visitors, the international team members have been selected for their expertise in human research protections and their firsthand experience in meeting AAHRPP's accreditation standards.

Ian Chen, MD, LLM, JSD

Executive Secretary, Human Research Protection Center
National Taiwan University Hospital
Taipei City, Taiwan
Accredited since December 2012

Seil Jang, BS, LLM

IRB Analyst/Assistant Manager
Samsung Medical Center
Seoul, Republic of Korea
Accredited since June 2006

B.I. Choe, PhD, MBA, LLM

Professor of Bioethics and Chair, Department of Institutional Review and Research Ethics
Associate Dean, Nicholas Cardinal Cheong Graduate School for Life
The Catholic University of Korea
Seoul, Korea
Accredited since June 2010

Meixia Wang, MD, PhD

Director of the Organization Office
Beijing You'an Hospital
Capital Medical University
Beijing, China
Accredited since June 2011

Hany Hamad, MBBS, MS

Chairman, Human Research Protections Department
King Fahad Specialist Hospital
Dammam, Saudi Arabia
Accredited since March 2014

Xiuqin Wang, MD, PhD

Deputy Director, Science and Technology Department
The First Affiliated Hospital with Nanjing Medical University
Jiangsu Province, China
Accredited since December 2013

From the President and CEO

ELYSE I. SUMMERS, JD

Helping you transition to single IRB review

One of AAHRPP's primary roles is as a resource. We feel an obligation to keep you informed on emerging trends and regulatory issues and help you respond to the changing research environment.

With that in mind, we have formed a work group to anticipate and address some of the challenges research organizations can expect as the research enterprise continues to transition to single or central IRB review for multisite studies.

As you know, the National Cancer Institute and National Institute of Neurological Disorders and Stroke already rely on central IRBs. In June, the National Institutes of Health (NIH) issued a final policy that requires use of single IRBs for all NIH-funded multisite U.S. studies. That policy takes effect in May.

Our work group includes representatives from AAHRPP-accredited organizations across the research enterprise: universities and academic medical centers, large hospital systems, smaller regional hospitals, VA centers, and independent IRBs. The group is headed by Michelle Feige, MSW, LCSW-C, AAHRPP Executive Vice-President, and Megan Kasimatis Singleton, JD, MBE, CIP, Associate Director, Human Research Protections at the University of Pennsylvania (AAHRPP-accredited since March 2007).

Members are drawing on their own experience, best practices, and existing models for collaboration to draft recommendations on how organizations can successfully share the responsibility for protecting research participants. The group also will consider issues specific to AAHRRP and our accredited organizations. For example:

- What does AAHRPP expect of accredited organizations when they are involved in an NIH study where the IRB of record is not AAHRPP accredited?
- Should AAHRPP draft a single, comprehensive guidance document or tip sheet that covers all related AAHRPP requirements, including an organization's role and responsibility when relying on another IRB or serving as the central IRB?
- Although AAHRPP standards already address single IRB review, do they need to be updated? Are there new or additional expectations that AAHRPP standards should specifically address?

Although these are complex issues, our job is made easier by the fact that so many AAHRPP-accredited organizations are leaders in our field and have extensive experience partnering on multisite studies. And we're not the only ones who feel that way. A prime example is the Cancer MoonShot 2020 decision—highlighted in this issue of Advance—to require that its IRB of record be AAHRPP accredited. That's good news for AAHRPP-accredited organizations and, even more, for research participants.

Also in this issue, we ask you to mark your calendars for our 2017 conference, which will be held May 9 to 11 in Detroit, a city that's near and dear to my heart. Please note that we are accepting proposals for conference sessions and, in a departure from the past, welcome participation from individuals from "not-yet-accredited" organizations and from consultants knowledgeable in human research protections. More information is available **here**.

I encourage as many of you as possible to **submit proposals**. Our conference has earned a reputation as a "must attend" for those involved in research protections. Much of the credit belongs to our presenters, who typically include some of the brightest stars in our field. Our thanks to all of you!

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

Save the Date: 2017 AAHRPP Conference

2017 AAHRPP CONFERENCE

Evolving, Adapting, and Thriving in the New Research Environment

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

Registration begins: November 1, 2016
To learn more and register, visit www.aahrpp.org.

Learn about:

- Thriving in a Changing Research Environment
- Adapting to Single IRB Review
- Evolving Patient-Centric Approaches to Research
- The Ethics of CRISPR (genome editing) Research
- And much more!

Other highlights:

- Social hour and poster presentations on innovative practices
- Network with friends and colleagues

Who should attend? Individuals from non-accredited and accredited organizations, international organizations, researchers, organizational officials, IRB professionals and chairs, compliance professionals, sponsors, patient group leaders, government, industry, voluntary health agencies, and community groups.

Where? The Westin Book Cadillac, 1114 Washington Blvd, Detroit, MI 48226