AAHRPP ADVANCE
One Standard Worldwide
WINTER 2015

Transitioning to Single IRB Review

The trend toward using single, or central, IRBs to oversee multisite studies is gaining momentum. AAHRPP provides education and information to help HRPPs prepare for the transition. LEARN MORE

A Conversation With NIH's Christine Grady, M.S.N., Ph.D.

AAHRPP invites Dr. Grady, an international voice in human research protections, to share insights on two complex research protection issues: informed consent and international research. LEARN MORE

Tackling Research Protection Issues—Together

President and CEO Elyse I. Summers, J.D., emphasizes AAHRPP's role as a resource for accredited and not-yet-accredited organizations. She encourages the human research protection community to work with AAHRPP to address today's research protection challenges. LEARN MORE

Annual Conference: Register NOW

Join us in Chicago May 19-21 at our annual conference for researchers, organizational officials, HRPP professionals, IRB members and chairs, sponsors, and others interested in comprehensive human research protections. Register by March 13 to pay the early bird rate. LEARN MORE

Upcoming Webinars

Watch for announcements about AAHRPP's educational webinars. Experts will discuss single IRB review for multisite studies, patient-centered outcomes research, and vulnerable populations. LEARN MORE

WINTER 2015

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Latest Accreditations

- **Albert Einstein Healthcare Network,** Philadelphia, Pennsylvania
- **China Medical University Hospital,** Taichung, Taiwan
- **Faculty of Medicine Siriraj Hospital, Mahidol University,** Bangkok, Thailand
- **Marshfield Clinic,** Marshfield, Wisconsin
- **National Marrow Donor Program,** Minneapolis, Minnesota
- **Pearl IRB,** Indianapolis, Indiana
- **St. John's National Academy of Health Sciences,** Bangalore, India

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

From the President and CEO

ELYSE I. SUMMERS, J.D.

Tackling research protection issues—together

To most in the research community, AAHRPP is synonymous with accreditation—and rightfully so. We are the world's leading accrediting body, the "gold seal," for human research protection programs. Yet to think of AAHRPP only in terms of accreditation is to miss the mark.

Like you, we have a much broader goal: to advance high-quality, ethically sound research that ultimately leads to new knowledge and public benefit. AAHRPP pursues that goal, in part, by serving as a resource for accredited and non-accredited organizations alike. We encourage the human research protection community to work with us to address questions not just on accreditation standards but also on global trends in research involving human participants. With extensive contacts in academia, government, and industry—and more than 200 AAHRPP-accredited organizations worldwide—we are in an excellent position to connect you with the appropriate experts and move the discussion forward.

In this issue of *Advance,* for example, we provide an update on the National Institutes of Health (NIH) proposal to require single institutional review board (IRB) review for NIH-sponsored multisite research. We also share insights from NIH's Christine Grady, M.S.N., Ph.D., on some of the complexities of informed consent and international research. And we remind you of our upcoming annual conference, a must-attend event for those concerned with human research protections.

The conference, "Looking Back and Looking Forward: Compliance, Collaboration, and Community," will be held May 19-21 in Chicago. As you can see from the conference **program**, this year's sessions tackle some of today's most pressing research protection issues, including different perspectives on single IRB review, IRB considerations in social media, comparative effectiveness research, and biobanking and large data sets. As in the past, we are offering a full-day preconference workshop for those interested in pursuing AAHRPP accreditation.

For the first time, the conference includes a session, in Mandarin, on lessons learned from AAHRPP accreditations in China and Taiwan. Also new this year are awards to acknowledge exceptional "AAHRPP ambassadors." We will be presenting a lifetime achievement award as well as awards for best AAHRPP site visitor and best AAHRPP site visit team leader.

Whether this will be your first AAHRPP conference or your 11th, you will benefit from opportunities to network, learn the latest news about research involving human participants, and, perhaps most important of all, join your colleagues in promoting excellent, ethical research.

I look forward to seeing you in Chicago.

Best regards,

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

Transitioning to Single IRB Review

AAHRPP offers tips for lead and relying IRBs

The trend toward empowering single, or central, institutional review boards (IRBs) to oversee multisite studies is gaining momentum. The National Cancer Institute (NCI) and National Institute of Neurological Disorders and Stroke already rely on central IRBs, and the Department of Health and Human Services, Food and Drug Administration, and Office for Human Research Protections have all endorsed the single IRB model. Most recently, in the strongest indication to date, the National Institutes of Health (NIH) proposed that all NIH-funded, multisite U.S. studies use single IRBs.

Although the policy is not final, many in the research community expect that NIH ultimately will require single IRB review whenever appropriate. AAHRPP and others generally back this position. But AAHRPP takes it a step further by providing education and information to help IRBs prepare for the potential change.

Three sessions at the upcoming AAHRPP **conference**—"Central IRBs: Opportunities and Challenges–Real and Perceived," "Single IRB Review: View From the Independents," and "Creating Efficiencies Through Collaboration: NeuroNEXT and IRBshare"—address many of the most pressing questions about single or shared IRB review. In addition, AAHRPP offers a **tip sheet** to help organizations reap the benefits of single IRB review while maintaining a high level of protection for research participants.

"Although there is a lot yet that NIH needs to sort out regarding the content, parameters, and implementation of any requirement in this realm, the overall idea to add efficiency and speed the review and approval of high-quality, ethically sound research is undeniably a good idea whose time has come," says Elyse I. Summers, J.D., AAHRPP President and CEO. "Many of the issues should be resolvable through due diligence, transparency, and communication."

A written agreement

One of the first, most important steps is to delineate in writing the roles and responsibilities of all organizations involved. Specify, for example, that the lead IRB is responsible for conducting the review in accordance with all applicable laws, regulations, and—for AAHRPP-accredited organizations—AAHRPP standards. Similarly, spell out that the relying IRB will inform the lead IRB of any local context issues, disclose relevant financial conflicts of interest, and comply with the requirements and determinations of the lead IRB.

The AAHRPP **tip sheet** details eight responsibilities that typically fall to the lead IRB, 16 to the relying IRB and organization, and four that may be delegated to either the lead or relying IRB. The sheet is not meant to be overly prescriptive or all-inclusive. Instead, it is intended to help IRBs identify and resolve potential stumbling blocks.

Building trust via AAHRPP accreditation

For many IRBs, the greatest challenges revolve around trust, in part because each organization has its own policies and procedures for complying with research protection regulations. Many organizations are uncomfortable ceding control to another entity without assurances of quality.

"That's where AAHRPP can ease the way," Ms. Summers says. "For multisite studies, the selection process for the lead IRB is paramount. The IRB of record must be of high quality and exist within a robust human research protection program—and that's exactly what AAHRPP requires of its accredited organizations."

To earn AAHRPP accreditation, an organization must demonstrate that it has the necessary infrastructure—from policies and procedures to education and monitoring—to help ensure that research is conducted in a scientifically and ethically sound manner.

Because AAHRPP accreditation is the gold standard for research protections, many organizations take accreditation status into account when choosing research partners and selecting an IRB of record. For this reason, Ms. Summers has asked NIH to consider either requiring or recommending AAHRPP accreditation for organizations that wish to serve as the IRB of record for NIH-funded multisite studies.

She points to two of the most significant endorsements of AAHRPP's standards: the decisions by both the NCI central IRB and the NIH intramural program to attain AAHRPP accreditation.

"We believe that the logical next step would be for NIH to expand this commitment to its extramural program," Ms. Summers says. "That could increase organizations' confidence in the quality and qualifications of the single IRB and help improve the process for the review and approval of research involving human participants."

A Conversation With NIH's Christine Grady, M.S.N., Ph.D.

Insights on informed consent, international research

Today's human research protection issues are more complex than ever. The scientific and technological advances that have the potential to drive extraordinary discovery also raise new concerns and present new twists on old challenges for those responsible for safeguarding research participants.

To help human research protection professionals understand and tackle two of these, AAHRPP recently asked the National Institutes of Health's (NIH's) Christine Grady, M.S.N., Ph.D., to share her perspective on informed consent and research around the world.*

An international voice in human research protections, Dr. Grady is Chief of the NIH Clinical Center's Department of Bioethics. She is a member of President Obama's Commission for the Study of Bioethical Issues, a Senior Research Fellow at the Kennedy Institute of Ethics, and a Fellow of both the American Academy of Nursing and the Hastings Center. Dr. Grady has a bachelor's degree in nursing and biology from Georgetown University, a master's degree in community health nursing from Boston College, and a doctoral degree in philosophy and bioethics from Georgetown University.

CHRISTINE GRADY, M.S.N., PH.D.

Informed consent

Dr. Grady describes obtaining informed consent as a perennial issue that is easy to understand in theory but difficult to achieve in practice. The central objective is to present the type and amount of information that people need and are entitled to, without overwhelming them with details. "Some of my own work has focused on what research participants comprehend," Dr. Grady says, "how carefully they listen and how well they understand the study and what they've agreed to."

One of Dr. Grady's studies sought to compare the effectiveness of standard consent forms and concise ones, all of which were approved by the institutional review board (IRB). On average, the concise forms had 63 percent fewer words. The study relied on questionnaires to assess participants' comprehension and satisfaction with the information they received. In the cohorts studied so far, comprehension was about the same for both groups, and satisfaction levels were equally high.

"There is always more information that can be provided," Dr. Grady says, "but more is not necessarily better." Yet consent documents continue to get longer and more complicated, in part because of concerns about complying with federal regulations.

"Increasingly, over the last few decades the focus has been on making sure that all the regulatory boxes are checked and that documents are part of the consent process," Dr. Grady explains. "That has created a level of burden and a compliance mentality, and the intent of informed consent has often gotten lost in the shuffle." She points to her experience with another randomized consent form trial involving multiple research centers and IRBs. For the sake of the comparative study, the IRBs were asked to keep changes to a minimum, if possible. "Ninety percent of the consent forms were changed," Dr. Grady recalls. "In almost every case, the revised forms were longer and had higher reading levels than the templates."

She reminds IRBs that "one way to protect people is to make sure they understand what they're being asked to do" and urges IRBs "to be thoughtful in the way they advise investigators on the consent process."

Newer consent challenges: Data sharing, biospecimens, and comparative effectiveness research

Some of today's most complex consent questions stem from promising advances in fields such as data science and biomolecular technology. How, for example, should researchers obtain consent without knowing what the data or biospecimens might be used for in the future? When are new activities covered by the original consent? Some in the research community have proposed broad consent as a solution, "but it's controversial," Dr. Grady says. "We're not finished with this discussion."

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Discussion also proceeds on concerns related to pragmatic clinical trials and comparative effectiveness research. Despite agreement on the need to assess the effectiveness of some widely used interventions, there is considerable debate about the type of information that should be shared with patients/participants.

"Since the interventions are already approved and already in use, some argue that the research is not subjecting participants to additional risk," Dr. Grady says. "The question remains: What do we tell them? In these cases, is informed consent simply telling participants that we want to make sure two different interventions are equally effective? Or do we have to tell participants everything we know about each intervention?"

International research

Dr. Grady's work in international research has concentrated on effective partnerships and the nature of collaboration. With colleagues at the NIH, she developed principles and benchmarks for ethical research in developing countries.

A key ethical consideration, spelled out in both the Declaration of Helsinki and the Council for International Organizations of Medical Sciences guidelines, is that participants and the host community or nation share in the benefits of the research. "At the very least, there ought to be some justification for why the research is being conducted in that particular community—how the research findings could address an issue that's important to the community or lead to an intervention that could be adopted there," Dr. Grady says. "The motivation shouldn't simply be that it's cheaper or easier to conduct the research there."

Equally important are respect for the participants and communities involved and understanding of cultural values and societal practices. These should be incorporated into the study design and implementation, including the process for informed consent. A truly collaborative partnership—with equitable representation from researchers, policymakers, and communities in developed and developing countries—can play a meaningful role in addressing these and other ethical matters.

** The views expressed are Dr. Grady's and not those of the NIH, the Department of Bioethics, or the Department of Health and Human Services.*

AAHRPP's Standard for Informed Consent

The AAHRPP standard for informed consent is covered by Element II.3.F., under Section II-3:

The IRB or EC approves each research protocol or plan according to criteria based on applicable laws, regulations, codes, and guidance.

Element II.3.F. states:

The IRB or EC has and follows written policies and procedures to evaluate the consent process and to require that the researcher appropriately document the consent process.

AAHRPP does not mandate how the standard must be met. Instead, AAHRPP gives organizations the flexibility to address the standard in their own way. Following is some guidance for those applying for AAHRPP accreditation:

IRBs should evaluate and "know the circumstances of the consent process, such as who will conduct the consent interview, the timing of obtaining consent, and any waiting period between informing the participant and obtaining consent, and based on this information determine whether the criteria for approval of research are met."

Written application materials should include:

- Waiting periods between informing prospective participants and obtaining their consent
- The language used by those obtaining consent
- The person who will conduct the consent interview
- Steps taken to minimize the possibility of undue influence

More information can be found on Pages 93-98 of the **Evaluation Instrument** for Accreditation.

2015 AAHRPP Conference: Register NOW!

Looking Back and Looking Forward: Compliance, Collaboration, and Community

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

Join us in acknowledging the evolution of research protections—from government shut-downs and calls for reform to successful self-policing via AAHRPP accreditation to the establishment of global norms and best practices.

May 19-21, Chicago

Highlights include sessions on:

- Single IRB review of multisite studies
- Biobanking and large data sets
- Patient-centered research (engagement)
- Social media research
- Comparative effectiveness research
- Finding flexibility in the informed consent process
- Lessons learned from international accreditations—presented in Mandarin

Registration

Early bird registration rate available through March 13.