AAHRPP ADVANCE
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MARCH 2016

Preparing for Single IRB Review? Start with a Strong HRPP

The move toward single IRB review of multisite studies increases the likelihood that you will be asked to entrust research review to another organization. In those instances, you still will be responsible for protecting participants. How well you fulfill that responsibility will depend, in large measure, on the quality of your HRPP.

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Responding to the Changing SBER Landscape

Technological advances are creating exciting opportunities and raising new questions for those involved in social, behavioral, and education research (SBER). Penn State shares its approach to tackling some of today's challenges. LEARN MORE

Marking a Milestone for Accreditation, Research Participants

President and CEO Elyse I. Summers, JD, highlights the progress made since AAHRPP's founding 15 years ago. She also discusses the findings of a recent survey of accredited organizations, including high marks for the value of accreditation and support for changes to the reaccreditation process. LEARN MORE

Register Now for Annual AAHRPP Conference

There's still time to register for the 2016 AAHRPP Conference, which will be held April 19-21 in Long Beach, California. Get the latest information on research protection issues, and join us as we celebrate the 15th anniversary of AAHRPP's founding.

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MARCH 2016

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Upcoming Webinars

- **April 26 and 28:** Evaluating IRB Members and Chairs: Basic and Innovative Solutions for Meeting Standard II.1.B.
- **July 26 and 28:** HRPP Metrics: Discussion of AAHRPP Data and Trends from 2015
- **October 25 and 27:** Measuring the Quality and Process of Informed Consent

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Read AAHRPP's comments on the NPRM.

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

Preparing for Single IRB Review? Start with a Strong HRPP

If your organization participates in multisite studies, at some point you will be asked—if you have not been asked already—to entrust the research review to a single or central institutional review board (IRB). Even when your organization does not serve as the IRB of record, you bear responsibility for protecting participants. And how well you fulfill that responsibility will depend, in large measure, on the quality of your human research protection program (HRPP).

"It's important to understand that when you cede IRB oversight, you are ceding only one component: the ethical review of the research," says Scott Lipkin, DPM, managing director at FTI Consulting, working in the Health Solutions practice and the Research and Compliance Group. "The institutional oversight and control—the conflict-of-interest review and management, investigator credentials and training, review of adverse affects and unanticipated problems—remain the responsibility of your organization."

A former member of AAHRPP's Council on Accreditation, Dr. Lipkin has conducted more than 25 AAHRPP site visits. He also spearheaded the AAHRPP accreditation effort at Lehigh Valley Health Network, where he served as chief research officer. Recently, Dr. Lipkin shared his insights during the AAHRPP webinar "Transitioning to Single IRB Review: Keeping Your HRPP Strong."

Dr. Lipkin's message reflects AAHRPP's emphasis on a comprehensive, systematic approach to research protections. Since its inception, AAHRPP has required organizations to extend the responsibility for research protections beyond the IRB to the larger HRPP and the research organization as a whole. In fact, some HRPPs—and some AAHRPP-accredited organizations—rely entirely on external IRBs for research review.

Under these circumstances, the organizations are evaluated on how well they meet the standards of Domain I (The Organization) and Domain III (Researcher and Research Staff). For the most part, the standards for Domain II (Institutional Review Board or Ethics Committee) are satisfied by using an external IRB of another AAHRPP-accredited organization.

The expectation is the same when your organization relies on an external IRB. As an AAHRPP-accredited organization, you are required to continue to meet the **standards** of Domains I and III. In the process, you will help safeguard participants and protect your organization.

The AAHRPP Advantage

Supporters of single IRB review say that it could further the long-term goal of improving public health by advancing high-quality research. They point to benefits including streamlined processes, reduced administrative burden, and stronger, standardized protections for research participants.

U.S. government and industry research sponsors have begun encouraging—and, in some cases, requiring—single IRB review for multisite studies. The National Cancer Institute and National Institute of Neurological Disorders and Stroke already rely on central IRBs, and the National Institutes of Health (NIH) is planning on requiring use of single IRBs for all NIH-funded multisite U.S. studies. The recent notice of proposed rulemaking for revisions to the Common Rule includes a similar requirement. "Single IRB review is the wave of the future, and now is the time to discuss it and focus on organizational preparedness," says Dr. Lipkin.

In this environment, AAHRPP accreditation provides significant advantages. To earn accreditation, an organization must demonstrate that it has the necessary infrastructure, or HRPP, to ensure that research is conducted in a scientifically and ethically sound manner. An AAHRPP-accredited organization can be confident that it has the systems in place to protect participants and comply with all rules and regulations—even when the organization is not acting as the IRB of record.

AAHRPP accreditation also plays a key role in eliminating a previous stumbling block to single IRB review: concerns about entrusting that oversight to another organization. "Accreditation confirms that the institution's IRB functions in accordance with the regulatory requirements. That adds a high degree of confidence," Dr. Lipkin says. "The difficulty lies in assessing the level of function of a nonaccredited organization's IRB."

AAHRPP has developed "**Tip Sheet 24**: Relying on an External IRB" to help organizations reach agreement on the responsibilities that will fall to the IRB of record and to the organization relying upon it. The online tip sheet also links to a detailed checklist to help in the evaluation of nonaccredited IRBs.

Responding to the Changing SBER Landscape

Technological advances—in data collection and analysis, electronic monitoring, online interaction, and more—are creating exciting opportunities and raising new questions for those involved in social, behavioral, and education research (SBER).

At The Pennsylvania State University (Penn State, AAHRPP accredited since 2006), for example, requests to process data use agreements have increased significantly over the past three years, and the agreements themselves have become more complicated. Research into social networks has changed dramatically. SBER researchers who previously used traditional data collection methods, such as surveys and interviews, now also analyze data gathered from mobile devices and social media websites. And the increased reliance on online education is prompting discussions on what defines a "classroom" and the resulting implications for informed consent.

How is Penn State addressing these issues? Sara Horn, CIP, assistant director of Penn State's Office for Research Protections, points to the human research protection program's (HRPP's) acceptance of change, emphasis on relationship-building, willingness to embrace flexibility, and commitment to continuous quality improvement.

"We have a responsibility to support innovation in research," Horn says. "The landscape is changing, and we're changing with it. That's important, particularly given that revisions to the Common Rule could be on the horizon."

IRB Transformation

To help position itself for continued success in an evolving research landscape, in 2013 Penn State began a major restructuring of its processes, HRPP organization, and electronic systems. Some of the changes, such as the purchase of an electronic system and HRPP toolkit, involved significant investments. Others, such as tapping existing institutional resources, could easily be adopted by organizations of any size.

The new system was launched on a pilot basis in December 2013 and implemented university-wide in July 2014. The result is a streamlined system that reflects both federal regulations and AAHRPP standards but dramatically reduces the burdens placed on researchers and institutional review board (IRB) staff. "A lot of IRBs are doing a lot more than they are required to, and our IRB was among them. We were also requiring investigators to do things one way—our way," Horn says. "Now, our policies and procedures reflect the flexibility that the regulations allow.

"Our staff and IRB members are empowered to make the decisions they need to make," she adds. "That approach can go a long way toward improving relationships with investigators."

Other outcomes data from both Penn State sites, University Park and Penn State College of Medicine, include:

- Improved turnaround times, comparable to those of other AAHRPP-accredited organizations (The average turnaround time for full IRB review has been cut in half.)
- Positive feedback from researchers and IRB staff
- A significant decrease in printing costs due to the adoption of a paperless system
- More efficient IRB meetings
- A successful AAHRPP site visit, resulting in zero observations and full reaccreditation

Forging and Tapping Relationships

This transition at Penn State was so effective, in part, because it involved constituents and tapped talent from across the university. For Horn, that emphasis on collaboration and relationship building is typical and has proved enormously helpful in navigating often-uncharted territory. "I have learned how important it is to build good relationships with individuals in areas such as information technology, information security, and risk management," she says. "These relationships are essential in ensuring that we have the necessary infrastructure to address IRB concerns about data storage and security."

Horn also has an invaluable partner in the College of Medicine. She has turned to her colleagues there for input on when FDA and other federal regulations might apply to SBER studies.

"We have researchers, for example, who are looking at the use of apps on personal electronic devices to treat or manage

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symptoms of mental health conditions," she explains. "When is an app considered a medical device, and under what circumstances do we apply the regulations? Our colleagues at the College of Medicine and elsewhere can help provide perspective on those questions."

Similarly, Horn has drawn on the expertise of the Flexibility Coalition, of which Penn State is a member, to draft policies that take advantage of the flexibility available in the federal regulations. She also believes in consulting with peer institutions on best practices for addressing emerging research issues.

Recently, for example, Horn reached out to other organizations that conduct food science research, which, under FDA guidance issued in 2013, could require the filing of investigational new drug (IND) applications. "We connected with other schools that have large food science programs to benchmark with them, discuss their approach, and share what we've done to improve our processes for handling those types of studies," she says. "We now provide additional support for investigators involved in FDA-related research, and that has helped immensely by creating a smoother process for the investigators and the IRB."

Accreditation and Continuous Quality Improvement

The additional support for FDA-related studies, ongoing collaboration, and IRB transformation are just three examples of Penn State's focus on continuous quality improvement. The university's 10-year record of AAHRPP accreditation is another example.

"We believe in continuous quality improvement, and our efforts to obtain and maintain accreditation over the years reflect that belief," Horn says. "AAHRPP accreditation is important no matter the focus or type of research conducted at an institution because it says a lot about the quality of our programs and our commitment to research participants.

"As the gold standard for high-quality HRPPs," she adds, "AAHRPP accreditation has enhanced the reputation of our program and institution as a whole."

From the President and CEO

Marking a milestone for accreditation, research participants

ELYSE I. SUMMERS, J.D.

This year, we mark the 15th anniversary of AAHRPP's founding, a milestone for all of us who believe accreditation makes a difference in the quality of research and the lives of research participants.

Back in 2001, one of AAHRPP's goals was to raise the bar for research protections and human research protection programs (HRPPs) across the United States and, ultimately, around the globe. Thanks in large measure to your support and commitment, AAHRPP has made extraordinary progress in achieving those goals.

Our site visitors repeatedly tell us how impressed they are with the quality of the HRPPs they survey, whether an organization is seeking AAHRPP accreditation for the first time or is pursuing reaccreditation. Little by little, AAHRPP accreditation is becoming the norm, not the exception. And that has had a positive impact throughout the research enterprise.

That doesn't mean our work is done. We continue to reach out to not-yet-accredited organizations as we strive for one standard worldwide for research protections. We also continue to look inward to identify ways that AAHRPP can improve. As you know, we expect AAHRPP-accredited organizations to commit to continuous quality improvement. It's only fair then that we require the same of ourselves.

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AAHRPP feedback survey

Many of you participated in our most recent quality improvement effort: a survey conducted in December to solicit your input on the value of accreditation, the improvements you've seen in your HRPPP since your organization earned accreditation, and whether we need to change the reaccreditation process.

We've posted the **results** on our website, and I'd like to share some of the highlights here:

- 93 percent of you are satisfied with the overall improvement of your HRPP as a result of accreditation.
- 90 percent are satisfied with your standing in the research community due to accreditation.
- 89 percent are satisfied with the value that AAHRPP accreditation has added to your organization.

However:

- 67 percent of you are satisfied with the amount of time required to achieve initial accreditation.
- 53 percent are satisfied with the amount of time spent on attaining reaccreditation.

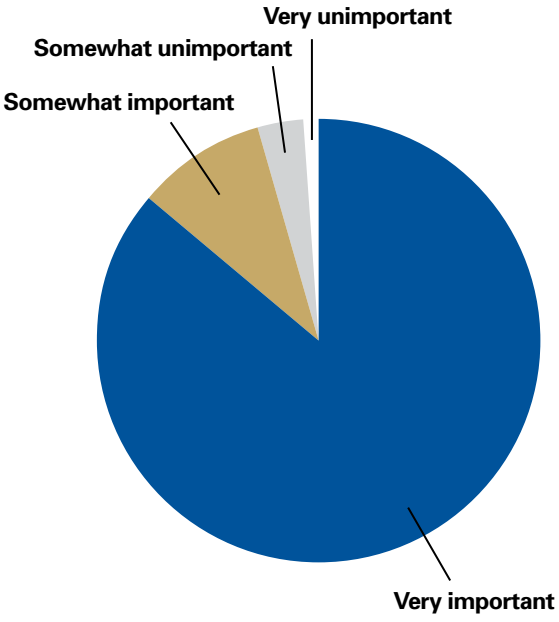
In many ways, these results come as no surprise: We are gratified at the overwhelming agreement on the value of AAHRPP accreditation. Yet we also recognize the need to move forward with plans to update the reaccreditation process. We intend to maintain our high standards and robust protections while reducing the burdens of the reaccreditation process, especially for legacy organizations that are approaching at least their second reaccreditation.

Robert Hood, Ph.D., who recently returned to AAHRPP as director of accreditation and operations, will be an integral member of the team overseeing the reaccreditation project. Many of you may remember Rob from his earlier tenure as associate director of accreditation. We are thrilled to have him back and encourage you to reach out to him in person next month during the AAHRPP **conference**.

Thank you for helping to make our first 15 years so successful. I look forward to celebrating AAHRPP's anniversary together at our conference in Long Beach.

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

How important was achieving AAHRPP accreditation to your organization?



Answer Choices	Responses	
Very important	**86.32%**	82
Somewhat important	**9.47%**	9
Somewhat unimportant	**3.16%**	3
Very unimportant	**1.05%**	1
Total		**95**

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2016 AAHRPP Conference: Register Today!

At the Crossroads: Harmonizing Ethics, Efficiency & Innovation

SAVE THE DATE

April 19-21, 2016
Long Beach, CA

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Learn about:

- The Changing Landscape of Research Oversight
- Innovations in Research Design
- Single IRB Review and the National Model Reliance Agreement
- Big Data, Genomic Research, and Privacy

Other highlights:

- AAHRPP's "quinceañera" party
- Opportunities to discuss best practices with colleagues and reconnect with friends

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? Hyatt Regency Long Beach, 200 South Pine Avenue, Long Beach, CA 90802