AAHRPP ADVANCE
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FALL 2015

Responding on Reaccreditation

Changes to reaccreditation underscore the beneficial, collaborative nature of the process. AAHRPP anticipates additional revisions, including a "reaccreditation with distinction" designation, in the months to come. **LEARN MORE**

AAHRPP's "Contracts" Standard, Simplified and Clarified

Updated guidance and a new contracts working group seek to reduce the burden of Standard I.8 while maintaining robust protections for research participants.
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Keeping Pace With an Ever-Changing Research Landscape

President and CEO Elyse I. Summers, J.D., discusses challenges and opportunities presented by today's research environment, AAHRPP's response as "AAHRPP 2.0," and the enduring value of AAHRPP accreditation. **LEARN MORE**

NPRM Comments Due December 7

Please join AAHRPP in responding to the notice of proposed rulemaking for revisions to the Common Rule. Comments are due by December 7 and may be delivered electronically, by mail, or in person. **LEARN MORE**

2016 Conference: Save With Early Registration

The 2016 AAHRPP Conference will be held April 19-21 in Long Beach, California. Early registration, at a reduced rate, has just begun. **LEARN MORE**

FALL 2015

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Latest Accreditations

- **Children's Mercy Hospital,** Kansas City, Missouri
- **Cliniques Universitaires de Bruxelles-Hôpital Erasme,** Brussels, Belgium
- **Cliniques Universitaires Saint-Luc,** Brussels, Belgium
- **Renal Research Institute, LLC,** New York, New York
- **Texas Tech University Health Sciences Center,** Lubbock, Texas
- **The Third Xiangya Hospital of Central South University,** Changsha, Hunan Province, China

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Responding on Reaccreditation

For the University of Kentucky (UK), AAHRPP reaccreditation probably could not have gone smoother. The Step 1 review identified very few items to address, and with the documentation portion of the process already complete, the site visit focused on more substantive issues.

"It was reaffirming," says Ada Sue Selwitz, M.A., Director of the UK Office of Research Integrity and Co-Director of the UK Center for Clinical and Translational Science. "The site visitors recognized our strengths and reinforced that we were doing well in certain areas. It's always gratifying to hear that from an outside organization."

This positive experience reflects UK's strong human research protection program (HRPP) and efforts to prepare for reaccreditation. To some extent, the experience is also the result of AAHRPP's recent changes to make the reaccreditation process more beneficial and collaborative.

AAHRPP President and CEO Elyse I. Summers refers to these changes half-jokingly as "AAHRPP 2.0." She is serious, however, about making reaccreditation less burdensome while maintaining an overriding commitment to research protections.

"AAHRPP 2.0 is well underway, and we're pleased that many organizations find value in the reaccreditation process and the progress we've made," she says. "But it's become apparent that we need to do even more—to make some meaningful changes to emphasize AAHRPP standards that assess the quality of the HRPP."

Since Ms. Summers became CEO in late 2013, AAHRPP has made the following changes to reaccreditation:

- Simplified the submission process, enabling applicants to provide documents via CD-ROM or USB flash drive.
- Streamlined the reporting forms for Step 1 and Step 2 to reflect items of greater relevance to organizations and AAHRPP's review process.
- Adopted an "early outreach" process for Step 1 reviewers, who now contact applicants shortly after they submit Step 1 documents in order to help organizations identify areas that need to be addressed prior to the site visit.
- Edited instructions for clarity and to help ensure a successful submission.
- Eased the schedule by giving organizations more time to prepare for site visits.
- Updated feedback forms to capture more useful information from organizations and site visitors.
- Added a new designation—"approval contingent upon …"—which permits reaccreditation for organizations that, despite otherwise strong programs, need to make minor adjustments to some elements.

Looking ahead, Ms. Summers intends to:

- Survey organizations that have been reaccredited at least once to solicit their input on the process.
- Further refine the annual reporting tool to collect more information on what works for organizations—and what can be improved.
- Develop a more robust post-site visit evaluation form for organizations to complete.
- Require refresher training for site visitors.
- Officially acknowledge areas of strength by adding "reaccreditation with distinction" as a potential outcome. The distinction designation already exists for initial accreditation.

A rigorous, valuable process

Some of the changes will be significant, but the process will remain comprehensive and rigorous. As UK's Ms. Selwitz discovered, that's what makes it valuable.

"Before reaccreditation, if you'd asked me, I would have told you that all of our policies and procedures were up to date and reflected the current regulatory framework," she says. "Reaccreditation forced us to take a closer look, and we found some things that needed fixing. There was nothing major, but without reaccreditation, we wouldn't have caught it."

Although UK begins official preparation for reaccreditation seven to eight months in advance, the university continually updates its AAHRPP application, adding policies as they are developed or amended. One year before reaccreditation, Ms. Selwitz begins talking about the process with faculty and administrators. Six months before, she begins publicizing opportunities for education.

"We use reaccreditation as a tool to educate everyone within the HRPP, to promote and strengthen our program," Ms. Selwitz says. "We don't see it as a burden, because if you use reaccreditation effectively, you will improve your program.

"I was pleased with the process and the outcome," she adds.

AAHRPP's "Contracts" Standard, Simplified and Clarified

Few standards have prompted more questions and concerns than I.8, which includes five provisions to help ensure protections for participants involved in sponsored research. AAHRPP is responding to these concerns with a two-pronged approach:

- Earlier this year, we developed additional guidance—including sample contract language—to help organizations meet this standard. The most problematic element has been I.8.E, in part because of misinterpretation of what the element requires. Many organizations mistakenly believe that I.8.E requires sponsors to provide additional monitoring for two years after a study is closed. In fact, however, the emphasis is on reporting. If, within two years after a study closes, a sponsor learns of results that could affect participants' welfare and safety, I.8.E requires that those results be communicated to the investigator or organization. The institutional review board (IRB) can then decide whether to notify participants.

  More detailed information is provided in **Tip Sheet 25**: Provisions in Contracts and Funding Agreements.

- More recently, AAHRPP created a contracts working group to take a harder look at Standard I.8 and consider adopting a more flexible approach to interpreting whether the standard is met. The working group includes representatives of those constituents most affected by this standard: universities and academic medical centers, independent IRBs, contract research organizations, and international organizations. Sarah Kiskaddon, J.D., M.A., AAHRPP Director of Global Development and Public Affairs, is a member of the working group, as is a Council on Accreditation member who also is an experienced AAHRPP site visitor.

"Standard I.8 is one of those rare instances when, in the interest of providing adequate protections, AAHRPP's requirements exceed U.S. regulations," Ms. Kiskaddon says. "We believe that the obligations set forth in the standard are appropriate. Research participants deserve to know trial results—both positive and negative. At the same time, we realize that this requirement is creating roadblocks that we did not intend."

A major goal of the working group is to find a solution to often lengthy negotiations, between organizations and sponsors, about the AAHRPP-required language.

"We're looking for ways to streamline the process, perhaps by prearranging language with sponsors," Ms. Kiskaddon says. "Our intent is to strike the right balance—to protect research participants without creating undue burdens that can have a negative effect on research."

The working group's recommendations are expected by year-end and will be passed on to AAHRPP-accredited organizations early next year.

From the President and CEO

Keeping pace with an ever-changing research landscape

ELYSE I. SUMMERS, J.D.

Like so many other disciplines, the field of research protections is in the midst of a transformation that is driven, in part, by technological innovation and an increasingly global enterprise. Many of us are affected by these changes almost daily. The nature of our work requires us to identify the latest trends and advances—Big Data, precision medicine, comparative effectiveness research, and more—and find the balance between potential benefits and potential risks.

Very often, we find ourselves traversing uncharted territory, with more questions than answers. Now, for the first time since 1991, 16 U.S. departments and agencies are tackling many of those questions by proposing revisions to the Common Rule—and asking us to weigh in. Responses to the notice of proposed rulemaking are due December 7. AAHRPP will be submitting comments, and we encourage you to do the same.

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We can't predict with specificity what an updated Common Rule might require, but we expect some significant revisions. And that's as it should be. A lot has changed in 24 years, and we all share the responsibility to respond thoughtfully. No doubt, the underlying motivation for the Common Rule—the ethical obligation to protect research participants—will remain the same. What could change is how we fulfill that obligation.

Albeit in different ways, we at AAHRPP are in a similar situation. Next year, it will be 15 years since we incorporated with the goal of advancing ethical research and strengthening protections for research participants. That goal and the vast majority of our standards and elements have stood the test of time. Even so, we see the need to update some practices in response to input that we've requested from you.

Making progress as AAHRPP 2.0

In the two years since I joined AAHRPP as president and CEO, I've spent a great deal of time reaching out to many of you and listening to what you'd like to see from what I've come to call "AAHRPP 2.0." What I've heard most often are requests for a more collaborative, supportive approach. In response, we at AAHRPP make the following pledge: If your organization aspires to or is committed to achieving accreditation or reaccreditation, we will work with you to make it happen.

Our pledge holds true for organizations seeking accreditation for the first time and for those pursuing reaccreditation. For the latter group, with the support and encouragement of our Board of Directors, we're considering a major overhaul of the reaccreditation process, especially for clients who have already been reaccredited at least once. Our intent is to make changes that balance robust protections with procedures and processes that not only don't add burden but, in fact, relieve it.

You'll see a similar approach to one standard that has proved difficult for many accredited organizations: Standard I.8. As you read on page 3, we've already provided additional guidance on I.8 and have established a contracts working group to review the standard with an eye toward increasing flexibility of interpretation.

We also are calling for refresher courses for site visitors who haven't had AAHRPP training in recent years. If your organization is AAHRPP accredited, you know that we require ongoing education for institutional review board (IRB) members and researchers so they can keep up with an ever-changing landscape. We should expect nothing less of ourselves.

NPRM Comments Due by December 7

As you know, the U.S. Department of Health and Human Services and 15 other federal departments and agencies are proposing the most significant amendments in decades to the Common Rule. Comments on the notice of proposed rulemaking (NPRM) are due December 7 and may be delivered electronically, by mail, or in person.

The goal of the NPRM is "to better protect human subjects involved in research, while facilitating valuable research and reducing burden, delay, and ambiguity for investigators." Proposed changes tackle some of today's most complex issues: informed consent, including requirements for biospecimen research; exempt activities; and single institutional review board (IRB) review for cooperative research.

Many organizations, including AAHRPP, intend to submit comments. We urge as many of you as possible to weigh in and help shape the regulations that will affect research and participants for years to come.

Enduring value of the "gold standard"

Such adjustments are typical of organizations of AAHRPP's age and stature. In the 15 years since our founding, AAHRPP has earned a place at the forefront of advocacy for research participants and high-quality research. Like any successful organization, we will retain that place by meeting the changing needs of those we serve.

AAHRPP will continue to fill a void where regulations and guidance are silent on research protections. We also will continue to step up and "put some meat on the bones" of regulations where there is little or no guidance. However, where clear regulatory language and guidance spell out a government agency's view, AAHRPP standards should not be interpreted to require greater than what the regulations require.

The value of AAHRPP accreditation, and reaccreditation, is stronger than ever. AAHRPP accreditation remains the gold standard for research protections worldwide. To government agencies and research organizations, AAHRPP accreditation signals that you are committed to compliance and are a trusted research partner. In the current research environment, with many changes afoot, that message resonates as never before.

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

2016 AAHRPP Conference: Save With Early Registration

At the Crossroads: Harmonizing Ethics, Efficiency & Innovation

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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