

AAHRPP ADVANCE

WINTER 2010

Enhancing Protection for Research Participants

APRIL CONFERENCE IN ATLANTA

Focus on Final Revised Accreditation Standards

The talk of this year's AAHRPP annual conference in Atlanta, April 12-14, will most likely turn on how organizations can meet the Final Revised Accreditation Standards after they are required of all applicants on March 1, 2010.

From beginning to end, the conference will present at least 11 pre-conference workshops, plenary sessions, in-depth symposia, and breakout sessions that will allow you to focus on how the revised standards apply to your organization. See page 7 for all of the topical areas that will be covered at the conference.

Applying for accreditation and reaccreditation

The pre-conference workshop, "Getting Started Toward AAHRPP Accreditation," guides you in using the revised standards to assess your organization, as a first step toward application for accreditation. And the breakout session, "Fundamentals of Accreditation for New Applicants," helps you complete that application.

You can get an overall perspective of the standards in the "Review of the Final Revised Accreditation Standards" session as well as learning more detail about "Mastering Organizational (Domain I) Responsibilities in Your HRPP" and "Training Clinicians to Meet Research Responsibilities."

A session on using electronic systems to help you achieve accredi-

Sessions on Final Revised Accreditation Standards

- Getting Started Toward AAHRPP Accreditation
- Fundamentals of Accreditation for New Applicants
- Review of the Final Revised Accreditation Standards
- Mastering Organizational (Domain I) Responsibilities in Your HRPP
- Training Clinicians to Meet Research Responsibilities
- Leveraging Your Electronic Systems to Meet the Accreditation Standards
- Preparing for and Earning Reaccreditation
- Providing Equivalent Protections in Transnational Research
- Current Perspectives on Conflict of Interest
- Community-based Participatory Research
- Protections for Adults Who Have Diminished Decision-making Capacity

tation—and one on reaccreditation itself—will show you how to maintain your seal of Full Accreditation.

The Final Revised Accreditation Standards have put particular focus on crucial areas of human protection.

Using new Standards

One of the new standards is covered in the in-depth symposium, "Providing Equivalent Protections in Transnational Research," which is essential to expanding opportunities for quality, ethical research worldwide.

Another standard deals with conflict of interest. The plenary session on "Current Perspectives on Conflict of Interest" explores both individual and organizational conflicts of interest and how to keep them from creating bias in human research.

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AAHRPP®

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

Fewer Burdens, More Protections

Research organizations around the world can now achieve and maintain accreditation through a process that is more efficient, flexible, and supportive than ever before—and more rigorous in ensuring the safety and welfare of those who participate in research.

Nowhere will this advance to the next level of excellence be more evident than at AAHRPP's annual conference in Atlanta this year. (See page 7 for topics that will be discussed.) Eleven sessions at the conference deal explicitly with applying the Standards that go into effect March 1 for all applications for accreditation. (See front cover.)

Attend the conference from April 12 to 14 and you will learn how the Standards are now streamlined and easier to understand. They also improve protections for participants in transnational studies and for all participants when it comes to individual and organizational conflicts of interest.

More time between accreditations

AAHRPP has also decided to lengthen the period of accreditation for organizations—once they have been reaccredited for the first time—thus allowing them to devote more resources to their HRPPs. (See page 3.) At the same time, organizations will meet more rigorous reporting requirements during the period between reaccreditations, in order to ensure that they are in compliance with the accreditation standards.

Organizations can also increase efficiencies that both reduce the

Organizations can also increase efficiencies...by conducting a thorough self-assessment before writing their applications. See page 4 to learn how AAHRPP accreditation directors can help you conduct the self-assessment more thoroughly and efficiently than you might if your organization tried to do it alone.

burden of resources required to apply for accreditation and lead to stronger protections, by conducting a thorough self-assessment before writing their applications. See page 4 to learn how AAHRPP accreditation directors can help you conduct the self-assessment more thoroughly and efficiently than you might if your organization tried to do it alone.

Checking or unchecking

Another opportunity to reduce burdens while increasing protections arises when organizations conducting government-sponsored research decide whether to check the boxes on the Federal-wide Assurance form. (See page 6.) One HRPP director says it's more efficient to be accredited and devote resources to protecting all participants than to have to report every problem among all studies, whether or not they receive government support.

Most clinical studies in the U.S. are conducted at small research sites, often in community hospitals with fewer than 100 protocols at any given time.

And so, AAHRPP is particularly proud that two more hospitals, along with four other organizations, raised the total number of organizations accredited by AAHRPP to 200 in December. (See page 5.)

The place for hospitals and other organizations to find out more about how to advance their human research protection programs to the next level of excellence—so that they use resources most efficiently to protect participants—is the Atlanta conference.

Page 7 lists conference sessions that will explore strategic issues, applying the standards, quality improvement, social and behavioral science, IRB functions, and industry-sponsored research in an environment where you can share experiences, exchange knowledge, and help your organization become even better at what all of us must do so well.

— Marjorie A. Speers, Ph.D.

Organizations Have Five Years Between Reaccreditations

Fewer burdens, more rigorous reporting

Accredited organizations now have five years between their first reaccreditation and subsequent reaccreditations. The change, which maintains the three-year period from initial accreditation to the first reaccreditation, is part of AAHRPP's effort to reduce burdens on organizations while maintaining the rigor of the reaccreditation process.

The longer reaccreditation period will apply to currently accredited organizations after their next reaccreditation. Beginning on January 1, 2010, accredited organizations are also being asked to supply more specific information in their annual reports and to follow new procedures that may require status reports and limited site visits to resolve any outstanding noncompliance with AAHRPP standards.

The option of mandatory site revisits has not been changed, according to the revised accreditation procedures issued by AAHRPP.

Annual report

Previously, the annual report required of all accredited organizations had to include the following information:

- A summary or table of major problems or deficiencies identified in the past 12 months and an account of how they were resolved.
- A brief description of all programmatic changes that positively or negatively influenced the Human Research Protection Program (HRPP).
- The results of any federal review of the HRPP.

The new annual report requirement focuses on specific information

in five categories that are likely to affect compliance with the Accreditation Standards:

1. Organizational changes in:

- The name of the organization.
- The ownership of the organization.
- The governance of the organization (e.g., President or Chief Executive Officer).
- The organizational official.
- The individual responsible for the day-to-day operation of the HRPP.
- The application contact for the HRPP.

2. Resource changes:

- A 10 percent or greater increase in the number of active research protocols over the amount of resources assigned to oversee protocols.
- A 10 percent or greater reduction in resources during the past 12 months, along with a description of how that reduction affects the HRPP.

3. Changes in program scope, reflecting:

- Any mergers or acquisitions.
- The addition of research not previously conducted or reviewed by the organization, such as planned emergency research, research involving children, or gene transfer research.
- The addition of functions, committees, or IRBs.

4. Changes in program delivery, such as:

- Using external IRBs.
- Contracting for the services of another organization.

5. Catastrophic events that result in an interruption or discontinuance of an HRPP or a component of the program.

In addition to annual reporting requirements, rules about other reporting have changed as well. An organization no longer has to report, preferably within 72 hours, inquiries from a government oversight office that could result in a for-cause investigation or findings or changes concerning its HRPP that might affect its ability to continue to meet the accreditation standards.

Within 24 hours

Any sanctions taken by a government oversight office still must be reported within 24 hours, as well as any lawsuits related to the HRPP. Organizations that fail to report government sanctions or to provide requested information may be placed in the Probation category or have their Accreditation Revoked.

The Council on Accreditation reviews reports of any events that substantially affect an HRPP and decides whether any further action must be taken, such as requiring additional information, requesting a status report, or conducting a limited site visit. If you are not sure whether to make a report to AAHRPP or what you should report, contact the organization at accredit@aaahrpp.org or (202) 783-1112 for advice.

Status report, limited site visits

The Council will now have as an option the ability to request a status

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Accreditation Directors Take the Anxiety

What thoughts occur to you when your organization first begins talking about accreditation?

- Our peers are getting accredited.
- Industry sponsors require accredited central IRBs and prefer accredited research sites.
- Accreditation looks like the wave of the future, and it's approaching fast. If we don't get accredited, we could miss out on funding for our research.

And then reality sets in:

- We don't have the internal resources to go through the accreditation process—leaders' support, staff, infrastructure, time, and dollars.
- We don't know where or how to begin.

One thing can help you put those thoughts to rest: While AAHRPP conducts a rigorous application process, its accreditation directors also provide support to help you think through what you need to do to strengthen your human research protection program (HRPP) during your self-assessment, before you even start writing your application.

Help with your self-assessment

Conducting a thorough self-assessment has always been the key to writing a good application for accreditation. Many organizations, however, think they have to do it all by themselves. That's not true.

It is a little-known fact—especially among smaller research sites like community hospitals—that once you signal your commitment to accreditation by prepaying your

application fee, you become a client and can use the expertise of our accreditation directors to help you:

- Demystify the application process with objective information.
- Clarify any questions or confusion you have about the standards or the application process itself.
- Think through your own approach to meeting the standards and elements.
- Ask the right questions of your organization during your self-assessment.
- Identify the information you need to supply in your application.

"Mike took the tension out of our self-assessment and the rest of the accreditation process," says the Director of Research Participant Protection at one community hospital about Assistant Director of Accreditation Michael Pagliaro, R.N.

"Even though it looked rather daunting at first, Mike provided a steady, helpful hand as we moved through the process," reports Scott

J. Lipkin, D.P.M., F.A.C.F.A.S., from the Lehigh Valley Health Network in Allentown, Pennsylvania.

Learning how to learn

Mike and our other directors will not give you the answers. They don't have templates you can use to fill in the blanks. Instead, they will ask questions that help you discover your own answers and help you learn from accredited organizations how they handle issues like yours, which came up during their self-assessments.

"The directors help you learn how to achieve the level of the best human research protection programs," says Peter S. Vasilenko, Ph.D. and Vice President of Accreditation at AAHRPP. "They will help you work through problematic issues and help you develop enhanced policies, procedures, and practices."

AAHRPP's President and CEO agrees. "People do not learn when you give them the answers you think they should give," says Marjorie A. Speers, Ph.D. "We want organizations

Rebecca Clark • ASSISTANT DIRECTOR OF ACCREDITATION With experience from community hospitals

Rebecca M. Clark, B.S., came to AAHRPP in 2008. She has experience with community hospitals, where she found answers to the challenges associated with underfunded research programs.

Mike Pagliaro • ASSISTANT DIRECTOR OF ACCREDITATION With experience from government-sponsored research

Michael Pagliaro, R.N., had been serving researchers and the people who participate in studies for 22 years, before joining AAHRPP in 2007 to work with our clients.

Mike was the Research Subject Advocate for a major government research program for eight years and served for 14 years as a study coordinator and clinical research nurse for the same program.

Out of the Application Process

to become experts in learning how they can maintain compliance and continuously improve their HRPPs.”

For organizations that are concerned about the resources required to become accredited, “the whole application process becomes less burdensome when clients and consultants work with us during the self-assessment,” according to Assistant Director of Accreditation Rebecca M. Clark, B.S.

Less burden, stronger program

Some organizations haven’t heard how AAHRPP has streamlined the Standards, lengthened the accreditation period from one reaccreditation to the next, and improved client service. And they haven’t experienced how helpful an accreditation director can be.

“Having a relationship with an accreditation director early in the process is much more efficient for organizations because it helps them empower themselves to strengthen their programs,” says Mr. Pagliaro.

“We have always offered this service to organizations once they become clients,” says Nicholas C. Slack, M.B.E. and Associate Director of Accreditation at AAHRPP. “But few have taken advantage of it. They should know that they can.”

At the 2010 conference in Atlanta, you can experience how AAHRPP accreditation directors could work with your organization as you complete your self-assessment. They will be available for one-on-one discussions throughout the meeting.

You can also get more information now on becoming a client and working with an accreditation director by calling (202) 783-1112 or sending an e-mail to accredit@aahrpp.org.

Nick Slack • ASSOCIATE DIRECTOR OF ACCREDITATION With experience from industry-sponsored research

Nicholas C. Slack, M.B.E., knows how to work with research sites funded by industry sponsors.

Before coming to AAHRPP in 2008, Nick worked for an independent IRB, serving investigators and research staff at universities, hospitals, and government agencies, as well as manufacturers and clinical research organizations.

Peter Vasilenko • VICE PRESIDENT OF ACCREDITATION With experience from research, oversight, and accreditation

Peter Vasilenko, Ph.D., knows research, oversight, and accreditation from the perspective of a researcher, IRB member, HRPP director, and as a site visitor and member of the Council on Accreditation at AAHRPP.

He directed the HRPP at a research-intensive university, where he led a team that achieved accreditation in 2006, before joining AAHRPP in 2008. Peter has served on university and hospital IRBs as both a member and chair, and he conducted research on infant mortality for 17 years.

Hospitals Join Accreditation Trend

Following the trend, two hospitals joined four other organizations in December to bring the total number of clients accredited by the Association for the Accreditation of Human Research Protection Programs to 200.

Accredited organizations represent nearly 1,000 entities.

Here is the list of newly accredited organizations:

- **HealthPartners Research Foundation**, Minneapolis, MN
- **Independent Investigational Review Board Inc.**, Plantation, FL
- **Liberty IRB, Inc.**, DeLand, FL
- **South Shore Hospital**, South Weymouth, MA
- **Spectrum Health**, Grand Rapids, MI
- **The University of North Carolina at Chapel Hill**, Chapel Hill, NC



To Check or Uncheck the FWA Boxes

Checking the boxes on the Federal-wide Assurance (FWA) form can impose significant regulatory burden without adding any substantive protections for participants, according to leaders of human research protection programs (HRPPs).

Some say it might even prevent many kinds of research from taking place in the biomedical sciences and particularly in social, behavioral and education research (SBER).

“When a research organization checks the boxes on its FWA form, all of the research conducted by that organization, regardless of whether it has been funded by the Department of Health and Human Services (DHHS), is open to inspection by the Office of Human Research Protections (OHRP),” Marjorie A. Speers, Ph.D. and AAHRPP President and CEO, explains.

When an organization does not check the boxes, OHRP may inspect only research studies that are funded by DHHS.

Accreditation, on the other hand, allows an organization to uncheck the boxes, avoid excessive burden, and still ensure that participants in all types of research are protected as well as, if not better than, federal regulations require.

Excessive burden

“We simply cannot afford to devote the resources needed to meet all the reporting requirements mandated by the government,” says the Director of the Human Research Protection Program at one major university.

“We might still report, but we need to limit what we’re compelled to report,” she says.

Furthermore, many human research protection administrators are not convinced that the requirements that apply when the boxes

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are checked actually increase protections for participants. They argue that, in fact, the burden of work that goes into reporting takes resources away from overseeing research studies.

Subparts B and A

The regulations that come into play when the FWA boxes are checked were written primarily with clinical research in mind. Thus, if an organization checks Subpart B of the FWA, for example, it will not be allowed to conduct SBER studies that involve pregnant women, because any study involving pregnant women is required to advance biomedical knowledge.

In addition, many other federal regulations make perfectly good sense in clinical research, but not necessarily in SBER. Some regulations dealing with consent issues, categorization of risk, and permissible categories of research in studies that involve participants from vulnerable populations, such as children or prisoners, for example, do not make SBER ethically sound.

Checking Subpart A adds greater burden, for example, when it requires an assurance of compliance and IRB review of any school, nursing home,

community center, or other venue where the organization has no active role in the research study other than to provide access to the study population.

Accreditation verifies protection

AAHRPP has designed its standards to apply as much to protecting participants in SBER as they apply to protecting those in biomedical research.

When organizations have unchecked the boxes, AAHRPP allows them to provide protections that are appropriate to the level and nature of the risk involved in the study and meaningful to the type of research.

Under the accreditation standards, an organization could require that the results of a SBER study that includes pregnant women, for example, must contribute to general knowledge or knowledge that is beneficial to society, rather than to biomedical knowledge.

AAHRPP takes no position

“AAHRPP takes no position on whether to check or uncheck the boxes,” says Dr. Speers. “If an organization checks the boxes, it must comply with the federal regulations in order to meet the accreditation standards and, if it does not check the boxes, it must still apply protections equivalent to federal regulations, in order to earn and maintain accreditation.”

This means that a research institution that conducts different kinds of research can leave the boxes unchecked, meet all federal regulations, limit the burden of OHRP oversight to federally funded research, and provide the best available protections to participants in its research studies.

Get ready for the new world of HRPPs at this year's **AAHRPP Conference**

April 12-14, Atlanta

Learn, discuss, and network, while you advance your organization to the next level of excellence.

Strategic issues

- Advancing Your HRPP to the Next Level
- Funding HRPPs and Research in the Current Era of Health Care Reform
- Trends in HRPPs for VA-sponsored Research
- Maintaining Quality with Diminishing Resources
- Marketing Your Accredited Research Organization to Sponsors
- Working with the Federal Agencies

Applying the Standards

- Getting Started Toward AAHRPP Accreditation
- Fundamentals of Accreditation for New Applicants
- Mastering Organizational (Domain I) Responsibilities in Your HRPP
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- Current Perspectives on Conflict of Interest
- Community-based Participatory Research
- Providing Equivalent Protections in Transnational Research
- Review of the Final Revised Accreditation Standards
- Preparing for and Earning Reaccreditation
- Engaging the Community in Planned Emergency Research
- Protections for Adults Who Have Diminished Decision-making Capacity

Quality improvement

- Charting Improvement Using Quality Indicators
- Has the Incidence of Noncompliance Increased?
- Contingency Planning for HRPPs
- Implementing Metrics for Your HRPP
- Leveraging Your Electronic Systems to Meet the Accreditation Standards
- Educational Activities that Enhance the HRPP

Industry-sponsored research

- Multisite Research: Does Review by One IRB Adequately Protect Research Participants?
- Crisis Responses in Phase 1 Trials
- Negotiating Care and Cost Coverage for Research-related Injury in Sponsored Research

Social and behavioral science

- Improving Relationships Between the IRB and Social Scientists
- On the Fringe of Human Research: Oral History, Journalism, Business, and More
- Waivers of Parental Permission in Behavioral and Social Science Research
- Are Behavioral and Social Science Research IRBs Really Different from Biomedical IRBs?

IRB functions

- Building Collaborations Between Organizations and Their IRBs
- Exerting Flexibility
- Problems, Adverse Events, Protocol Deviations, and Noncompliance: When Are They Unanticipated Problems Involving Risks to Participants or Others?
- Tough Exempt Determinations
- Evaluating IRB Chairs, Members, and Staff

If these topics interest you, contact us on the Web at www.aahrpp.org to learn more and register for the conference.

We will be updating these topics with the final program agenda before the conference. So please check our Web site.

AAHRPP ADVANCE

Published quarterly by the Association for the Accreditation of Human Research Protection Programs, Inc.

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Editor:
David Ward

Design: Levine & Associates, Inc.
Washington, DC

Printing: Todd Allan Printing, Co., Inc.
Beltsville, MD

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Reaccreditations

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report that will inform the Council about the activities an organization is pursuing in order to achieve compliance with a standard about which the Council has a specific concern or in order to report on the progress of transitions within an HRPP.

The Council may also request a limited site visit when it wishes to verify compliance with the standards or resolution of areas in transition.

AAHRPP usually notifies the organization of the need for a limited site visit when the Council places it on Probation or in the Accreditation-Pending or Reaccreditation-Pending categories. AAHRPP may also require a limited site visit following the Council's review of a status report.

NEWS & NOTES

The federal Office of Human Research Protections (OHRP) has made accreditation one of the factors it considers when deciding which institutions it selects for not-for-cause compliance evaluations.

The updated guidance, "Compliance Oversight Procedures for Evaluating Institutions," says that institutions will be selected based on the following considerations, in addition to their status of accreditation "by professionally recognized human subject protection program accreditation groups."

- Volume of DHHS-conducted or -supported research in which they are engaged.

- Whether they have a history of a relatively low level of reporting to OHRP under the requirements of DHHS regulations at 45 CFR 46.103(b)(5).
- The need to evaluate implementation of corrective actions following a previous for-cause compliance oversight evaluation.
- Geographic location.
- And status of recent human subject protection evaluations or audits by other regulatory agencies (such as the FDA) or recent participation in quality improvement programs (such as OHRP's Quality Improvement program).