AAHRPP Accreditation: Gold Standard and Standard Practice

In the four years since the founding of the Association for the Accreditation of Human Research Protection Programs (AAHRPP), the move toward accreditation has surpassed expectations. Sponsors, federal regulating bodies and other government agencies, and voluntary health agencies now acknowledge that accreditation holds research organizations to a higher standard — offering the best protection for research participants and promoting quality research. As a result, organizations in all sectors of the research enterprise, both nationally and internationally, are seeking accreditation.

Already, 28 organizations representing 88 entities nationwide have earned accreditation, demonstrating their commitment and adherence to a “gold standard” for research. Among them are community hospitals, teaching hospitals, and cancer centers; independent IRBs; research institutes; and universities. Another 210 organizations are working toward accreditation, and, over the next four years, all of the nation’s major research organizations will have completed the accreditation process.

These statistics provide compelling proof that accreditation is fast becoming the standard of practice. At the same time, they underscore AAHRPP’s critical role in ensuring accountability among research programs, safeguarding research participants, and promoting quality research.

Indicators of success
AAHRPP’s progress is evident in the response across the research enterprise and from those it represents.

Candidates for accreditation
- Nearly 80% of academic medical centers either have already earned accreditation or have begun the accreditation process. These leaders in research are raising the bar for ethical standards and creating pressure for others to follow suit.
- Other universities whose research portfolios are primarily behavioral and social science also are seeking accreditation, as are teaching hospitals, community hospitals, independent IRBs, government agencies, research sites, and clinical research organizations.

Stakeholders
- Leaders in the research community have joined AAHRPP as Supporting Members (see AAHRPP Welcomes First Supporting Members, Page 8) and are urging organizations engaged in research to pursue accreditation as an assurance of quality.
- Some of the strongest support is evident in the government’s own actions. The Department of Energy, the Department of Health and Human Services, and the Department of Defense are seeking accreditation for their intramural research programs.

The Office for Human Research Protections (OHRP) and the Food and Drug Administration plan to inquire about accreditation status in their proposed IRB registration system. OHRP already takes accreditation status into account in prioritizing its not-for-cause compliance visits.

Sponsors and other funding agencies recognize that accredited organizations have more efficient operations, provide better and more comprehensive protections of research participants, and produce high-quality data. Accredited...
The market has spoken.

Loudly and clearly it has opted not just for accreditation but for accreditation by AAHRPP.

As of November 15, 2005, the Partnership for Human Research Protection (PHRP) ceased operations, leaving AAHRPP as the sole national and international accrediting body for research organizations. Some have mistakenly interpreted PHRP's dissolution as a sign that accreditation has not taken hold in the field of human research. In fact, as the article on Page 1 indicates, the reverse is true. Accreditation not only is alive and well but is fast becoming standard practice — with AAHRPP serving as the standard-bearer.

Our success is no accident. It is rooted in the philosophy and approach of AAHRPP, undertaken since our founding members joined forces in 2001 to create an accreditation program. From the start, these seven organizations — Association of American Medical Colleges, Association of American Universities, Consortium of Social Science Associations, Federation of American Societies for Experimental Biology, National Association of State Universities and Land-Grant Colleges, National Health Council, and Public Responsibility in Medicine and Health — were clear about their intentions for AAHRPP. Above all, AAHRPP would safeguard research participants by promoting sound, ethical research. It would raise the bar in human research protection. And it would establish itself as the program of choice through an accreditation process based on self-assessment, peer review, and education.

The market recognizes the added value that this model and AAHRPP bring to the accreditation process and the research enterprise. As evidence, we need only look to the ever-increasing list of accredited organizations and the recent decision of seven organizations to join AAHRPP as Supporting Members. (See story, Page 8.)

An enduring commitment

Organizations that attain AAHRPP accreditation do so, in part, because of their commitment to continued improvement. AAHRPP supports this commitment through ongoing education. A prime example is our annual conference, which is highlighted on Page 7. The conference, “Quality Human Research Protection Programs,” is geared toward accredited and non-accredited organizations and stakeholders and provides a wealth of information about accreditation and about practices that improve protections for research participants. This year we are offering four special tracks for those who prefer to focus on a specific area of interest.

“Weour success is no accident. It is rooted in the philosophy and approach of AAHRPP, undertaken since our founding members joined forces in 2001 to create an accreditation program.”
**Welcome New AAHRPP Board Members:**

Nancy Neveloff Dubler, L.L.B.
Montefiore Medical Center

Sandra Harris-Hooker, Ph.D.
The Morehouse School of Medicine

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**“Clarifications” on Web Site**

A new “Clarifications” section on the AAHRPP Web site provides Council on Accreditation explanations of its interpretation of accreditation standards. Clarifications will be updated each quarter, after the Council on Accreditation meeting.

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**Now in Publication**

Two members of the Council on Accreditation and one member of the Board of Directors have authored books on ethics in research.

- **Is There an Ethicist in the House?**
  **On the Cutting Edge of Bioethics**
  
  Jonathan D. Moreno, Ph.D.  
  (Council on Accreditation Member)  
  Indiana University Press

  Dr. Moreno tackles some of today’s most important clinical ethics questions, addressing them with a clarity and insight that will be welcomed both by medical professionals and by lay readers seeking to understand the philosophical foundation of contemporary medical issues. He draws on his own experience as a hospital ethicist and discusses his understanding of bioethics, in theory and in practice.

- **The Ethics and Regulation of Research with Human Subjects**
  
  Carl H. Coleman, Jerry A. Menikoff, Jesse A. Goldner (Council on Accreditation Member), and Nancy N. Dubler (AAHRPP Board of Directors Member)  
  LexisNexis Publishing

  This book offers a comprehensive overview of the ethical and regulatory structure governing research with human subjects in the United States, as well as an in-depth exploration of a broad range of ethical and policy questions. It includes numerous excerpts from articles by leading scholars, advisory commissions, and others. It also features more than 700 notes and questions that guide the reader in developing an understanding of the subject matter. A reference work, the book can also be used as a course text with an accompanying teacher’s manual.

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**AAHRPP Accreditation**

CONTINUED FROM PAGE 1

organizations report that pharmaceutical companies have pre-approved them for clinical trials and waived inspections because of their accreditation status. Some voluntary health agencies that award grants now inquire about accreditation as part of the grant-making process. As accreditation becomes the standard, stakeholder organizations are expected to begin exerting pressure, requiring accreditation as a condition of research support.

**Behind the growth**

The push for accreditation reflects a heightened awareness of the benefits to the research enterprise as a whole. As the gold standard, AAHRPP accreditation serves as proof that an organization adheres to the highest ethical practices in protecting research participants. It helps build public trust and can lead to increased enrollment in research — and additional sponsor support.

The accreditation process itself also offers advantages and has been instrumental in securing AAHRPP’s place as the accrediting body of choice for those engaged in human research. The self-assessment that AAHRPP requires can lead to more effective utilization of staff and resources and can prevent costly shutdowns, problematic inspections, and misinterpretation of regulations.

Because AAHRPP standards exceed U.S. and international requirements for safeguarding research participants, accredited organizations must continually assess their research programs with an eye toward improvement. By seeking accreditation, they signal their willingness to raise and maintain the quality of their human research protection programs — and their long-term commitment to sound, ethical research.
University of South Dakota: Policies that Promote Compliance

The Research Compliance Office of the University of South Dakota (USD) — fully accredited by AAHRPP as of September 16, 2005 — has developed standard operating policies and procedures (SOPs) that stand out for their clarity and ease of application. As a result, they not only facilitate compliance with government regulations and USD requirements but also serve as a training tool for researchers who are new to the university.

According to Lisa Korcuska, Associate Director, Research Compliance at USD, the policies are the product of a more-than-two-year effort, including a review of best practices of other AAHRPP-accredited institutions. The SOPs also reflect Ms. Korcuska’s experience as a clinical trial coordinator and her desire that USD policies be “specific, yet easy to follow. What we want,” she says, “is to foster compliance.”

Ms. Korcuska offers the following tips to those who are drafting or updating SOPs:

1. Learn from others’ experiences. In addition to reviewing policies of other accredited organizations, USD purchased templates, complete with citations of applicable regulations, to use as the foundation for its own SOPs.

2. Keep language clear and concise. Ms. Korcuska enlisted non-researchers and non-IRB staff to read drafts of USD policies to make sure they were easy to understand.

3. Take a step back. After drafting a policy, let it sit for a few days. Return to it with a critical eye, and ask yourself if it does, indeed, say what you intended.

4. Routinely distribute policies and updates. USD researchers receive a binder with a complete set of SOPs. If a policy is updated, the Research Compliance Office announces the update via e-mail and attaches a copy of the revised SOP. Recipients can then print the revised policy and update their binders.

Information: Lisa Korcuska, lkorcusk@usd.edu, (605) 677-6067.

New CSMC Protocol Benefits Volunteers, Research Program

Volunteers for psychiatric research at Cedars-Sinai Medical Center (CSMC) — fully accredited by AAHRPP since April 20, 2004 — now benefit from an improved screening protocol that helps match participants with current clinical studies, identify and refer those in need of treatment, and build a registry of individuals who might be eligible and interested in participating in future studies.

The new, consolidated screening protocol replaces the telephone screenings that previously were conducted for each clinical study. It relies on 13 diagnostic tools to provide a more detailed assessment of prospective research participants.

By capturing significantly more information than can be obtained via phone, the consolidated screening can better identify individuals with the appropriate inclusion criteria for specific research studies. With volunteers’ consent, diagnostic and demographic information is maintained in a research database, making it easier to identify eligible individuals for future studies.

“In the past, we would perform pieces of this screening for every study,” explains Russell E. Poland, Ph.D., Director of Psychiatry Research at CSMC. “Now, we perform a comprehensive assessment that provides useful screening information for all existing studies and a much clearer diagnosis. We’re investing a lot more time in assessing subjects, but the additional information will help us in the long run.”

The information also is beneficial to participants, who receive a detailed report on their assessment, as well as referrals for CSMC or community-based services, when needed.

“The assessment is above and beyond what’s done by most practitioners, and it is provided free of charge, regardless of whether they qualify for a study,” Dr. Poland says. “In that regard, it’s a valuable community service.”

Information: Russell E. Poland, Ph.D., Russell.Poland@cshs.org, (310) 423-3533.
Insights into IRBs

Federal regulations define an Institutional Review Board (IRB) as a committee of “at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution.” The regulations require that an IRB “be sufficiently qualified through the experience and expertise of its members and the diversity of their backgrounds … to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects … and to ascertain the acceptability of proposed research in terms of institutional commitment and regulations, applicable law, and standards of professional conduct and practice.”

Despite the federal requirement for IRB oversight, tension sometimes exists between IRB professionals and investigators — and their different views on the role of IRBs in the research enterprise. In the Questions and Answers below, J. Michael Oakes, Ph.D., Assistant Professor of Epidemiology at the University of Minnesota, shares his perspective on IRBs as social institutions based on his research on IRBs. Dr. Oakes also is Chairperson of one of the university’s IRBs and is an active researcher subject to IRB review.

Q. How do most investigators or IRB professionals define an IRB?

A. In my experience, research investigators and IRB professionals typically have different, often opposing, views of IRBs. I find many investigators, particularly those in the social sciences, believe they should have free rein to conduct research without being subject to review. To them, the IRB is a bureaucratic hurdle to overcome. In contrast, most IRB professionals view the IRB as absolutely essential to ensure fairness for research participants and protection against potential self-interests. Not only is there tension between the two views, but this tension is increasing.

Q. How do IRBs function as social institutions?

A. Social institutions solve collective problems to provide “public goods.” In the case of IRBs, the public good is trust — for research subjects and for investigators. Each IRB review has implications beyond the specific protocol under consideration. Each review represents a collective obligation because it affects the trust required by all research participants, current and future. In much the same way, each review has the potential to influence investigators regarding a particular study, and studies nationwide, by providing assurances that all investigators are held to the same standard and that none can gain a competitive advantage by cutting ethical corners.

Q. What are the obligations of IRBs as social institutions?

A. There’s no question that the first responsibility of IRBs is to protect research participants — to review each research protocol and make sure there’s no coercion and no undue risk. But from the framework of social institutions, IRBs must also take steps to maintain the confidence of everyone involved: future researchers, future participants, and future funding agencies. The way to accomplish this is through consistency. AAHRPP plays an important role here because it ensures that IRBs from accredited organizations are following the same standards.

Q. What makes an IRB legitimate?

A. The short answer is fairness, accomplished through transparency and peer review. The latter is critical because it can address the tension cited earlier between the IRB and investigators. As the IRB profession increases in prestige, there appears to be a growing sense on the part of some investigators that their peers are no longer reviewing their research. That is not the case. Peer review on IRBs is done by other scientists and community members who fully comprehend the research. This peer review is an important part of the scientific process. It is as valuable and legitimate as the peer review required to submit an article for publication in a scientific journal or to apply for a federal grant. From a social institution perspective, one might predict tension between IRBs and researchers to abate if/when serving on the IRB is considered to be as prestigious as serving on an NIH grant review panel.
2006 Fee Schedule

AAHRPP has simplified its fee schedule for 2006. Both application and annual fees are now based only on the number of active protocols. A new category, “Level 0,” addresses the needs of organizations that rely solely on external IRBs for review, and contract for that review via AAHRPP-accredited organizations.

### 2006 Application Fee

<table>
<thead>
<tr>
<th>Program Size (based on number of active protocols*)</th>
<th>Application Fee (U.S. dollars)</th>
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</thead>
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<tr>
<td>Level 0 **</td>
<td>$5,500</td>
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<tr>
<td>Level 1 (1 – 100 protocols)</td>
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*The total number of active protocols is the sum of the number of protocols reviewed by the full IRB, the number reviewed by the expedited procedure, and the number of protocols granted exemption in the previous 12 months.

**Level 0: This fee category applies to organizations that rely entirely on the services of one or more external IRBs that are accredited by AAHRPP as part of another organization’s human research protection program.

### Newly Accredited Organizations Announced

The organizations listed here were awarded accreditation at the September 16 meeting of the AAHRPP Council on Accreditation.

The Council on Accreditation will meet again on December 16, 2005. A complete list of accredited organizations is available at www.aahrpp.org.

- University of Pittsburgh, Pittsburgh, Pennsylvania — Full AAHRPP Accreditation
- The University of South Dakota, Vermillion, South Dakota — Full AAHRPP Accreditation
- University of California, Irvine, Irvine, California — Qualified AAHRPP Accreditation
Don’t miss the second annual accreditation conference in Phoenix, Arizona, February 26 – 28, geared to individuals from both accredited and non-accredited organizations, including those working on accreditation or those who are new to the accreditation process. The conference is also targeted to stakeholders — government, industry, voluntary health agencies, and community groups — that are concerned with promoting human research protection and quality research. Institutional officials, IRB professionals and chairs, compliance professionals, researchers, sponsors, and patient group leaders should attend.

Information/Registration: www.aahrpp.org

Conference attendees will:
1. Learn to identify the key aspects of the accreditation process and acquire the skills to complete each phase.
2. Learn to identify the common problems organizations are experiencing in meeting the accreditation standards and ways to address them.
3. Become familiar with innovative practices to improve protections for research participants.
4. Interact with individuals from accredited organizations.

The conference dates are February 27 – 28. Pre-conference workshops will take place on February 26.

Main Conference:
Plenary Session Topics
- The Need for Partnerships in the Global Research Enterprise
- Legislative Initiatives Affecting Human Research Protection
- Ask Legal Counsel
- The Role of Voluntary Health Agencies in Protecting Participants
- Regulation and Guidance: Is There a Difference?

Breakout Sessions
Several special tracks are being offered during the breakout sessions for those who wish to concentrate on a particular topic:

Track #1 General accreditation procedures. This is a six-session series over the course of the two days focusing on how to conduct a self-assessment and review of the five domains of the accreditation standards.

Track #2 Accreditation procedures for behavioral and social science research programs. This is a six-session series over the course of the two days focusing on how to conduct a self-assessment with review of each of the five domains of the accreditation standards. This track will concentrate on issues specific to non-biomedical research programs.

Track #3 Industry-sponsored research. These six sessions will address:
- Industry audits and accreditation
- Clinical trials agreements
- Academic/industry partnerships
- International collaborative research
- ICH-GCPs, FDA, and DHHS regulations
- Safety monitoring

Track #4 This track is designed especially for institutional officials, and institutional officials will present the sessions.
- What is a human research protection program, and what organizational components are involved?
- What is the process of accreditation and to what am I signing on?
- What happens after the site visit?
- What will accreditation mean for the institution?
- Managing conflict of interest
- Reporting to regulatory authorities

In addition to these four tracks, there will be sessions on:
- Continuing review
- Non-compliance
- Unanticipated problems
- Suspensions/terminations
- Emergency research
- Streamlining the IRB process
- Research involving children
- Research involving cognitively impaired individuals
- Computer systems for IRBs
- Putting together the accreditation application
- Consent waivers and HIPAA
- Scientific review

Attendees may attend any of the breakout sessions. All breakout sessions are open to everyone.

Pre-conference workshops:

#1 Introduction to the FDA regulations — intended for those individuals who generally work with federally funded research

#2 Federal regulations and guidance — intended for those individuals who want to understand the federal regulations and guidance as they relate to accreditation

#3 Education programs for investigators, IRBs, and institutional officials — intended for those individuals who are interested in developing or enhancing educational programs

#4 Defining human subjects research under the federal regulations — intended for those individuals who wish to understand the DHHS and FDA regulatory definitions of research and human subjects, particularly as they relate to data collection activities on the boundary between research and non-research

This year, lunch will be provided. During the lunches, we will offer a networking session with accredited organizations on February 27 and topical roundtables on February 28.
AAHRPP Welcomes First Supporting Members

Leaders in research community promote accreditation

Seven leading organizations in the research community have joined AAHRPP as its first Supporting Members, lending their voices to those encouraging research organizations to seek accreditation.

As Supporting Members, these organizations will help AAHRPP further its mission to raise both the level of protection for research participants and the quality of research programs. They also send a powerful message to research organizations and the general public that accreditation is the right and smart thing to do.

The Supporting Members represent major voluntary health agencies and professional and educational associations. They include:

- AAALAC International
- Alliance of Independent Academic Medical Centers
- American Lung Association
- American Society for Investigative Pathology
- Leukemia & Lymphoma Society
- National Alopecia Areata Foundation

Their status as Supporting Members gives these organizations the opportunity to have input into AAHRPP’s accreditation program, such as nomination of site visitors and early input into accreditation standards. Equally important, their partnership with AAHRPP signals their unwavering support for sound, ethical research and their willingness to take a stand on behalf of human participants.

“Our supporting membership is a tangible indicator of our commitment to research, AAHRPP, and accreditation,” says Kimberly Pierce-Boggs, Executive Director of the Alliance of Independent Academic Medical Centers. “We have a fundamental belief not just in the importance of research but also in ensuring that it is conducted properly.”

For the Leukemia & Lymphoma Society, becoming a Supporting Member is a natural extension of the organization’s efforts on behalf of patients and their families.

“Our mission is to improve the quality of life for those with blood cancer and, ultimately, to find a cure,” explains Louis J. DeGennaro, Ph.D., Senior Vice President, Research. “Our support for AAHRPP and accreditation lets researchers know that we hold them to the higher standards set by AAHRPP. It also assures patients that their safety comes first.”