Responses to AAHRPP’s Proposed Revised Accreditation Standards started coming in the day they were released and have continued to arrive at standards.revision@aahrpp.org. Marjorie A. Speers, Ph.D., President and CEO, said she expects more comments to arrive through July 30.

“AAHRPP is gratified that the number and quality of comments match our diligence in writing the Proposed Revised Accreditation Standards,” Dr. Speers said.

Among other proposed changes, AAHRPP is asking organizations and the public to respond to stricter requirements proposed for conflict of interest, a proposed new Standard on conducting transnational research, a proposed Element on community-based research, and requirements concerning data safety monitoring.

“We aren’t suggesting any major revisions in the requirements for accreditation,” said Dr. Speers. “We simply want to ensure that our Standards continue to reflect current practice, respond to current concerns, and help move Human Research Protection Programs to the next level, including enhanced delivery of the benefits accredited organizations expect.”

Those benefits include:
- High standards of protections.
- An assurance of quality.
- Improved efficiency and effectiveness.
- A competitive edge.
- Government recognition.
- And improved public trust and confidence.

**Shorter timeline**

AAHRPP posted the first major revision of the Accreditation Standards since its founding at http://www.aahrpp.org/www.aspx?PageID=296 on June 1 and expects to have reviewed all comments ahead of schedule before October 1, when it will publish its Final Revised Standards. Accreditation applicants may use either the current Standards or the new Standards from October 1, through February 28, 2010. On March 1, all applicants will use the Final Revised Standards.

AAHRPP issued the first Accreditation Standards evaluating research protections and quality of research involving human participants in 2001. Since then, it has used them to accredit 188 organizations, including over 900 entities in universities, hospitals, and most recently the drug industry, when Pfizer earned accreditation for its clinical research units in the U.S., Belgium, and Singapore in March.

“While earning accreditation is still rigorous, we’ve reduced the workload on clients by clarifying language and reducing the number of items,” according to AAHRPP Vice President for Accreditation Peter Vasilenko, Ph.D., who is leading the revision process.
Interest in accreditation seems to be spreading among sponsors as quickly now as it did among academic research centers during the early years of AAHRPP. And with that interest, AAHRPP is continuing to improve the value it brings to all organizations working to ensure human research protection.

My conversations with various organizations indicate that many believe that other sponsors, besides Pfizer, are using only accredited independent IRBs and encouraging research sites to become accredited. Even so, many sponsors continue to believe that there is little difference between an accredited independent IRB, for example, and a non-accredited one (see story on page 6). It simply is not so, as the federal Government Accountability Office (GAO) “sting” proved so effectively to the House Subcommittee on Oversight and Investigations.

The worst news out of that hearing was that a fictitious IRB with a real dog as its CEO could attract business simply because the GAO registered it with DHHS.

**Big difference in quality**

There is a big difference in quality between an accredited independent IRB or research organization and one that has simply typed its name into the DHHS Web site.

And so, I am glad that we are helping Human Research Protection Programs (HRPPs) continue to improve quality by reviewing and proposing to make revisions to the original Accreditation Standards we first published in 2002. The Revised Accreditation Standards (see story on page 1) are as rigorous as before, and yet easier to use, because we have simplified language and streamlined the number and order of the Standards and Elements.

**Length of time between accreditations**

Additionally, we are evaluating the length of the accreditation period in response to requests from accredited organizations to extend the three-year period of accreditation. Send AAHRPP your comments on the accreditation period and on the Proposed Revised Accreditation Standards by July 30, at the latest.

You can access the Proposed Revised Accreditation Standards and comment forms at aahrpp.org, by clicking on the first bullet under “What’s New,” or go directly to http://www.aahrpp.org/www.aspx?PageID=296.

As an additional way to increase the value of the accreditation seal, by constantly improving quality at AAHRPP and helping our accredited organizations do likewise, we have been asking them to answer some new questions in the application and annual report forms.

We know it adds to the effort, but the information we collect will not only help our site visitors ask better questions; it will also allow organizations to demonstrate their superior quality when competing for funding.

**Texas and California systems add sister schools**

And lastly, we’re again proud of the efforts of 13 organizations that earned accreditation in June (see story and list on page 7), with The University of Texas Health Science Center at Houston and The University of Texas Health Science Center at San Antonio joining The University of Texas at Austin from The University of Texas System, and the University of California, Los Angeles, joining its sister schools in the University of California System: Riverside, Irvine, and San Francisco.

It is beginning to look as if related organizations are doing more to encourage each other to become accredited, and AAHRP is pleased to help make that a reality.

— Marjorie A. Speers, Ph.D.
AAHRPP and Others Focus on Conflict of Interest
Current Element could become a Standard

With the number of clinical protocols increasing overseas and the funding to conduct trials growing faster than federal funding for clinical research, the amount of money being spent to bring drugs to market has raised ethical questions.

And those questions are the focus of AAHRPP’s Proposed Revised Standard on conflict of interest (COI).

“By moving conflict of interest to a separate Standard, we are saying that it is a major function within a Human Research Protection Program,” explained Marjorie A. Speers, Ph.D., President and CEO of AAHRPP. “And the two Elements under that Standard then separate out specific aspects of conflict of interest.”

The Proposed Revised Standard on COI would require not merely that financial interests are reported, but that organizations have specific procedures and practices in place that identify, manage, minimize, or eliminate financial and other interests that might influence research.

Comment on Proposed COI Standard

The Elements under this Standard deal specifically with institutional and investigator financial interests, and with non-financial interests. AAHRPP has also added an Element in Domain II dealing with COI in regard to IRB members. (View and comment on the Proposed Revised Accreditation Standards at http://www.aahrpp.org/www.aspx?PageID=296.)

“We want to strengthen accreditation with greater focus on conflict of interest because it’s so important to eliminate bias, ensure the integrity of research, and protect human subjects,” Dr. Speers said.

The tension between money and responsible science was particularly evident in the past year, as the ranking member of the Senate Finance Committee, Charles E. Grassley (R-Iowa), investigated various allegations of conflict of interest. Those allegations ranged from investigators funded by the National Institutes of Health (NIH) to FDA decisions allegedly driven by political influence, and drug companies paying consulting fees to investigators who tout their products in academic journals.

Beyond NIH and FDA

In addition to calling attention to an NIH investigator who hadn’t reported substantial fees from a manufacturer, allegedly for praising its products in lectures at professional meetings, most recently Sen. Grassley has also criticized:

- The FDA for allowing a device-maker to market an annuloplasty ring without approval.
- Drug-makers’ gifts to nonprofit health organizations.
- And a medical journal article that allegedly made false claims and overstated the benefits of a product made by a company that paid the author during the time he conducted the study.

The House Subcommittee on Oversight and Investigations expressed similar concerns in March, as the Government Accountability Office charged that “the institutional review board system is vulnerable to unethical manipulation.” (See related story on page 6.)

Calls for reform

Both the Senate and the House are considering legislation that addresses the issue of conflict of interest in human research. At the same time, in separate reports, the Association of American Medical Colleges and the Association of American Universities, as well as the Inspector General of the Department of Health and Human Services, have called for reform.

In response to such public scrutiny, NIH is requesting public comments on whether it should strengthen regulation of both researchers’ and institutions’ financial interests.

The reason given for the request is the “increased potential of investigators to hold financial interests in multiple sources.”

Stronger regulation in six areas

NIH is considering whether to strengthen its regulations in the following six areas:

- Expanding the scope of the regulation and disclosure of interests to include Phase I SBIR/STTR applications, and whether investigators should be required to disclose all significant financial interests.
- Eliminating certain exemptions from the list of “significant financial interests” and adding other financial interests to the list.
- Increasing the rigor of the policies and procedures institutions use to identify and manage conflicts of interest.
- Enhancing enforcement of regulations against institutional non-compliance; requiring investigators to complete COI training; and requiring independent confirmation of institutional compliance through, for example, accreditation by a third party or an independent audit.
- Requiring organizations to provide additional information on identified conflicts.
- Putting in place new regulations that deal, for the first time, with institutional conflict of interest.
AAHRPP has begun collecting objective measures through questions in the application forms for accreditation and reaccreditation and annual reports.

These data will be used to guide site visits and signal to all organizations the types of information that they should collect to measure quality.

Answers to some of these questions will be used along with information the organization provides in support of the Accreditation Standards to form the basis of assessing the quality of Human Research Protection Programs (HRPPs).

“We are pushing the field to move in the direction of quality improvement,” according to Marjorie A. Speers, Ph.D., President and CEO of AAHRPP.

**Compare your organization**

Organizations can use the data to compare the quality of their HRPP with other research protection programs. And over time, organizations can use the data to judge their performance from year to year.

Accreditation is becoming the gold standard separating the best organizations from others. And the data AAHRPP has begun to collect on quality indicators can now help individual organizations understand where they have strengths and where they can improve the quality of their HRPP.

The initiative to create uniform quality indicators began in 2003 when AAHRPP received a grant from the Centers for Disease Control and Prevention (CDC) to develop measures of effectiveness of HRPPs. At the same time, organizations were implementing quality improvement activities in order to meet the Accreditation Standards.

As a result, today we have a growing consensus around the indicators that reflect quality in human research protection. Dr. Speers said that AAHRPP will continue to partner with its accredited organizations to further refine and establish standardized indicators of quality for HRPPs worldwide.

<table>
<thead>
<tr>
<th>High-Quality HRPPs Demonstrate</th>
<th>Indicators</th>
</tr>
</thead>
<tbody>
<tr>
<td>The commitment to human research permeates the entire organization, starting with senior leadership, who set the example by promoting ethical and productive human research.</td>
<td>The number of FTEs, dollars, and space devoted to the HRPP and the level of information technology in place. The average number of days from submission to initial review of protocols.</td>
</tr>
<tr>
<td>Researchers, IRB professionals, and others involved in protecting research participants communicate and collaborate to achieve a shared vision that emphasizes the importance of ethical human research.</td>
<td>The number of protocol deviations, cases of noncompliance, cases of serious noncompliance, and cases of continuous noncompliance.</td>
</tr>
<tr>
<td>The organization sets as a high priority to protect human research participants and safeguard their well-being.</td>
<td>The number and type of audits of the HRPP and IRB performed annually by the organization.</td>
</tr>
<tr>
<td>The organization advances discovery by publishing and sharing new knowledge, in order to help make available new treatments, new products for everyday living, and information to improve quality of life for all.</td>
<td>The number of publications, patents, copyrights, trademarks, or commercial products that involved research overseen by an organization’s Human Research Protection Program.</td>
</tr>
<tr>
<td>The consent process is honest and informative.</td>
<td>The number of complaints by enrolled participants that appear related to the participant’s not understanding the research study.</td>
</tr>
<tr>
<td>The organization manages conflicts of interest to preserve the integrity of human research.</td>
<td>Evidence of written documentation of policies and procedures to identify, manage, minimize, or eliminate conflict of interest.</td>
</tr>
<tr>
<td>The organization recognizes and fulfills its responsibility to the public by promoting community outreach and education efforts that help build public trust and support for human research.</td>
<td>Satisfaction of participants.</td>
</tr>
<tr>
<td>Researchers and IRBs view the Human Research Protection Program as efficient and effective.</td>
<td>The number of complaints from researchers and research staff, the number of complaints from IRB members, and researchers’ perception of IRB performance.</td>
</tr>
</tbody>
</table>
Organizations can still earn accreditation without collecting all of the data, but they must begin collecting this information before submitting their application for reaccreditation.

**The value of benchmarks**

As in health care and education, accredited organizations know the value of benchmarks in improving quality.

And simply collecting the data will provide the evidence needed to garner the internal resources required to improve the performance of the protection program. When an organization has benchmarks from AAHRPP showing how other accredited organizations perform against the same quality measures, it will know where to make adjustments.

Plus, the sooner an organization has the information in hand, the better it can use the information to seek government resources for research or convince private sponsors to select them. Funders will look for ways to make sure that the investment they make in an organization is well spent: that the level of quality they require is there and that they can count on it being there over time.

**Indicators of high quality**

The questions that appear on the application forms for accreditation and reaccreditation and annual reports came out of a desire on the part of AAHRPP to measure the characteristics of a high-quality HRPP. Those indicators are listed in the left column of the chart on the facing page. The questions AAHRPP is asking either in the Application Forms or in the Accreditation Standards that provide information on how well organizations are meeting the characteristics of a high-quality HRPP are listed on the right of the chart.

As AAHRPP collects those data over time, it will be able to create benchmarks against which organizations can measure their own performance, year to year. For many organizations, this is the first time they have thought about how to measure the performance of their Human Research Protection Program. For those who have quality improvement programs already in place, they are able to add the measures that they are not currently collecting. For others, they are facing challenges in transitioning their quality improvement activities to ones based on objective data. But, in the end, all recognize the importance and power of quantifiable data to improve quality.

**Proposed Revised Standards**

With input from AAHRPP's clients, Council on Accreditation, Board of Directors, and Standards Revision Committee, AAHRPP reduced the number of Domains covered by the Standards from five to three; the number of Standards themselves, from 22 to 15; and the number of Elements in the Standards, from 77 to 65.

**Strengthen and streamline**

According to Dr. Vasilenko, AAHRPP has:

- Consolidated redundant Elements.
- Divided any Element dealing with different topics into separate Elements.
- Clarified Elements that clients found difficult to understand.
- And expanded Elements to include transnational research, conflict of interest, community-based participatory research, and data monitoring.

“Our intent in revising the Accreditation Standards is to strengthen Human Research Protection Programs (HRPPs) and to streamline the accreditation process,” Dr. Speers said. “The Proposed Revised Accreditation Standards provide a more logical framework for an HRPP and better definition of the primary roles and responsibilities of the entities that comprise an HRPP.”

Both individuals and organizations may access and comment on the Proposed Revised Accreditation Standards at http://www.aahrpp.org/www.aspx?PageID=296. Or they may request a print copy by calling (202) 783-1112 or sending an e-mail for a print or electronic version to standards.revision@aahrpp.org.
Despite the fact that a fictitious independent IRB with a dog as its CEO could register with the Department of Health and Human Services (DHHS)—and that a bogus medical device company could use that registration to obtain a DHHS assurance of compliance—there’s strong evidence that many sponsors still think DHHS registration is a seal of DHHS approval.

It is not.

This thinking persists despite repeated statements that “Registered” does not mean “Approved” by Director of the Office for Human Research Protections Jerry A. Menikoff, M.D., J.D., at a recent hearing of the House Subcommittee on Oversight and Investigations.

But when the fake IRB advertised its services as “HHS Approved,” it had no trouble attracting a real company that wanted the IRB’s permission to add one of its clinics as a new test site for human trials involving invasive surgery. The nonexistent IRB could have authorized the testing, without any government oversight.

All IRBs are not the same

All IRBs registered with DHHS are simply not the same. And yet, conventional wisdom among many who hire independent IRBs is that “an IRB’s an IRB,” particularly if it is registered with DHHS.

Any IRB can approve research involving humans. Many IRBs can meet federal regulations required to receive government funding. Only accredited independent IRBs meet standards that exceed federal regulations by having in place written policies and procedures to ensure quality and ethical research practices.

Government agencies are fairly good at finding problems when something prompts an inspection. They are less effective at preventing problems, because they don’t evaluate IRBs before they are allowed to review research. The AAHRPP accreditation process, on the other hand, probes deeply into an independent IRB to make sure it has those written policies, embodied in written procedures that require best practices.

**Four kinds of deficiencies**

The most common problems government regulators uncover when inspecting IRBs involve four kinds of deficiencies:

- Inadequate initial or continuing review.
- Inadequate records.
- Inadequate written procedures or failure to follow them.
- Inadequate membership rosters.

The only effective way to prevent those problems is to have and use standard operating procedures that ensure the problems don’t occur in practice. Because if they do occur, then the sponsor of the study under review by an IRB with those problems is just as liable as the IRB itself.

In fact, AAHRPP reported in the spring edition of AAHRPP ADVANCE that FDA inspectors found fewer problems in research conducted by investigators at accredited organizations than in research conducted by investigators at non-accredited organizations.

“The difference in inspection findings indicates clearly that accreditation is a marker for regulators,” AAHRPP President and CEO Marjorie A. Speers, Ph.D., reported. “And that marker is a clear indicator that organizations associated with AAHRPP maintain better documentation and conduct higher-quality research programs,” Dr. Speers maintains.

In the end, while accreditation ensures compliance, it also does something more. In addition to demonstrating “proof positive that a sponsor takes responsibility and concern for participants and patients seriously,” according to an industry executive, it also produces high-quality IRB reviews, encourages greater competency among investigators, enhances participant enrollment in trials, leads to consistency across organizations, and perhaps most important, raises the overall quality of research.

**Ethical, efficient, quality research increases earnings**

All of those benefits affect both the cost structure and revenue of a sponsor. Accreditation requires transparent policies and procedures that ensure efficiency within a research enterprise, from within the company and extending to each strategic partner, including IRBs, clinical research organizations, and research sites. Increased efficiency lowers costs.

Merely writing down and enforcing such policies and procedures can...
increase efficiency. But each of the benefits of accreditation also drives revenue, by increasing perceived quality, leading to greater trust that a company provides safe products and treatments to the public.

What happens when a sponsor chooses an IRB that translates the need for efficient use of time and resources into “speed” and “cheap”? And what happens when both speed and lowest cost eclipse quality in the pharmaceutical industry?

Trust continues to plummet. Harris Interactive’s 2008 poll found only 26% of Americans saying they trust drug companies, and 52% saying they do not, placing drug companies just below the oil companies and just above tobacco, near the bottom of the list of industries Americans admire. Those numbers have continued to worsen over the past 10 years.

Reverse falling trust

Pfizer knows there is a way to reverse the slide. As part of a continuing initiative to demonstrate integrity and transparency, begun by Chairman and CEO Jeffrey B. Kindler two years ago, Pfizer wants to rebuild trust in its clinical trials. Accreditation of its Clinical Research Units around the world, requiring independent IRBs to be accredited, and encouraging its study teams to use accredited research sites are building blocks in that effort. (See AAHRPP ADVANCE, Vol. 6, No. 2, spring 2009, p. 1.)

Choosing strategic partners like accredited independent IRBs and research sites encourages everybody in the business of helping patients to keep their eyes on the prize: by doing not just the smart thing, but doing the right thing. In fact, accreditation has become the smart thing to do, simply because consumers believe that quality and ethics are the right things to do.

13 Organizations Earn Accreditation

The Universities of Texas and California add organizations

Thirteen new organizations earned accreditation from AAHRPP in June, including two that joined others in their university systems. The University of Texas Health Science Center at Houston and The University of Texas Health Science Center at San Antonio are joining The University of Texas at Austin as newly accredited organizations. And the University of California, Los Angeles, joins three others in the University of California System—Irvine, San Francisco, and Riverside—on the accredited roster as well.

In addition, one major hospital and another independent children’s hospital joined the ranks of organizations like theirs at AAHRPP, which has now accredited 188 organizations with more than 900 entities.

Newly Accredited Organizations

AWARDED JUNE 2009

Full Accreditation

- Beth Israel Deaconess Medical Center, Boston, MA
- G.V. (Sonny) Montgomery VAMC, Jackson, MS
- Louisiana State University Health Sciences Center – Shreveport, Shreveport, LA
- Nationwide Children’s Hospital, Columbus, OH
- Overton Brooks VA Medical Center, Shreveport, LA
- South Texas Veterans Health Care System, San Antonio, TX
- Southeast Louisiana Veterans Healthcare System, New Orleans, LA
- Syracuse VA Medical Center, Syracuse, NY
- The University of Colorado Denver, Denver, CO
- The University of Texas Health Science Center at Houston, Houston, TX
- The University of Texas Health Science Center at San Antonio, San Antonio, TX
- University of California, Los Angeles, Los Angeles, CA
- VA Eastern Colorado Health Care System, Denver, CO
Standards revision ahead of schedule

AAHRPP issued its Proposed Revised Accreditation Standards for public comment a month ahead of schedule, with a plan to allow applicants to begin using the Final Revised Standards beginning in October, rather than December. For copies of the Proposed Revised Accreditation Standards, as well as comment forms on them and possible changes in the accreditation period:

- E-mail your request to standards.revision@aahrpp.org.
- Access the AAHRPP Web site at www.aahrpp.org.

2010 annual conference

Plan to attend AAHRPP’s sixth annual accreditation conference, which will be held in Atlanta, Georgia, April 12–14, 2010, at the Omni Hotel at CNN Center. The Final Revised Accreditation Standards, planned for release in October, will be the centerpiece of this conference. See details at http://www.aahrpp.org/ www.aspx?PageID=201.

Webinars feature difficult issues

AAHRPP will conduct the first in a series of educational webinars that will discuss some of the more difficult issues, such as unanticipated problems, facing HRPPs, beginning this fall on the afternoon of October 1.

Peter Vasilenko, Ph.D., AAHRPP’s Vice President of Accreditation, will host the first webinar. If you have topics you would like to see discussed in subsequent webinars, you may suggest them to Dr. Vasilenko at pvasilenko@ aahrpp.org.

Correction

The spring 2009 issue of AAHRPP ADVANCE printed a chart on page 7 showing figures from the 2008 Clinical Investigator Inspection List, Center for Drug Evaluation and Research, Food and Drug Administration. The chart indicated incorrectly that 40% of investigators in non-accredited organizations received “Voluntary Action Indicated” findings from FDA inspectors. The correct percentage is 46.

OHRP issues FAQs

The Office for Human Research Protections (OHRP) has issued answers to a list of frequently asked questions (FAQs)—many of them providing guidance on IRB registration. The answers represent OHRP’s current thinking on IRB registration and “should be viewed as recommendations,” according to the notice published at www.hhs.gov/ohrp/IRBfaq.html.

Call (240) 453-6900 or (866) 447-4777 to discuss the FAQs with OHRP.