Accreditation in Clinical Research

Although accreditation has traditionally been reserved for the provider side of healthcare, researchers are no longer immune.

In fact, many of your colleagues have already begun to seek accreditation. On May 1, 2003, the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP), announced its first accredited research facilities. The Partnership for Human Research Protection (PHRP) followed suit, announcing its first accredited institution January 15, 2004.

Experts say the government strongly supports voluntary accreditation for clinical trials. This may mean your organization will be under increased pressure to seek accreditation in the next few years, and you will need to learn how to comply with new standards.

Although it may seem like a burden, accreditation can help you improve the quality of your research program—and consequently help protect your research subjects from harm. By helping you spot problems before a federal audit, accreditation can also keep your organization from being shut down by the government for noncompliance. The stamp of approval from an accreditor can also give your organization more credibility in the eyes of potential research subjects.

But you will need to work to comply with the standards, which will require a process of self-assessment and change. It will also mean additional expenses for your facility. It's time to educate yourself about what accreditation means and prepare to meet the standards.

The accreditors
AAHRPP and PHRP are the two organizations offering accreditation to human research protection programs.

AAHRPP, incorporated in 2001, was formed in the wake of government shutdowns at major academic research institutions. PRIM&R, one of the seven organizations that founded AAHRPP, has been pushing to develop accreditation standards for the past several years. PHRP is a partnership between two well-known accreditors, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the National Committee for Quality Assurance (NCQA).

Prior to the formation of PHRP, the NCQA had been working with the Department of Veterans Affairs (VA) on a research accreditation program since 2001. The NCQA was the first organization to offer clinical trials accreditation by establishing the contract with the VA.

Although it had originally planned to begin a commercial accreditation program early in 2003, the NCQA later partnered with the JCAHO to form PHRP. The PHRP draft standards were released in December 2002.

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Both AAHRPP and PHRP have issued standards that mirror existing federal regulations that have been in place since the 1970s. The two will likely compete for market share in the future.

**Making changes**

Self-assessment is the first step for organizations that undergo AAHRPP or NCQA accreditation. This process allows organizations to compare what they are doing with what the accreditation standards require and helps them understand what they will need to do in order to comply. AAHRPP self-assessments typically take between four and six months to complete.

Although accreditation standards devised by the PHRP and AAHRPP are based on existing federal regulations, many organizations will need to do a lot of work to comply with the standards. Many organizations still don’t comply with the federal regulations, experts say. The reasons are two-fold.

First, the guidelines can be confusing. Organizations don’t often receive a lot of guidance on what they should do, says Marjorie Speers, PhD, executive director of the Association for Accreditation of Human Research Protection Programs, Inc. (AAHRPP). That means they tend to repeat mistakes when it comes to compliance issues.

Second, policies are often oral rather than written as mandated by the government, says Cynthia Kenny, CMSC, CP, CIM, president and chief executive officer of IRB Specialists, Inc. Speers says this is one of the issues that many organizations seeking AAHRPP accreditation need to address.

Kenny offers other examples of problems she encounters at various research facilities, including lack of the following:

- Sufficient procedural manuals
- IRB minutes that accurately reflect meetings
- Standardized reporting forms for investigators

These items are mandated by federal regulations and new accreditation standards, but many organizations don’t know they’re required, she says.

Many organizations also lack internal tracking systems to record information about ongoing trials, according to Speers. If you’re not tracking your systems, it’s impossible to improve them, she says.

In addition to reinforcing federal regulations, accreditation from both organizations require compliance with the following:

- Organizations must provide education to staff and IRB members. Federal recommendations recommend but do not mandate such education, Kenny says. This requirement can mean your staff must subscribe to an educational publication, attend seminars, or take online courses.
- In many cases, accreditation will also mean additional oversight for research programs in many cases. Organizations will be called on to perform self-audits and review processes more carefully than they may have in the past.
- The standards would also require facilities to ensure that the number of IRBs is sufficient to handle the volume and type of research that occurs at the facility, says Kenny.

The bottom line is that accreditation will require people to change how they do things in order to comply with the standards, Kenny says.

**Budgetary impact**

The standards affect budgets in a number of ways. First, IRBs at small community hospitals often don’t have budgets, but would need to establish them.

The standards also mandate that organizations have sufficient staff and resources to provide proper oversight. In addition, research facilities will need to pay application fees for accreditation, as well as annual dues.

Application fees for the AAHRPP currently range from $7,700 to more than $25,300, depending on the number of protocols and IRBs at a particular facility. Fees are negotiated for organizations with more than 3,501 active protocols or three or more IRBs. Annual fees cost an additional $4,160–$10,400, depending on the size of the organization.

PHRP fees are also based on the size of the research program. A base price of $15,000 continued on p. 4
Accreditation includes the review of one IRB and the first 100 active protocols. Each additional IRB would cost $6,000, and each additional protocol costs $10. There are different pricing systems for health systems and individual or central IRBs.

The case for accreditation

Despite the work and expense that may be involved in meeting the standards, experts say there are many advantages to accreditation.

First, it will help provide uniformity among institutions. Right now there are vast differences from one research organization to another. Accreditation standards spell out how functions must be completed, and would therefore remove these inconsistencies, says Kenny. In addition, Speers says there are two more good reasons to consider accreditation:

- Many organizations are concerned about public trust in research. They believe that accreditation will help bolster the public confidence that research is safe.
- Nobody wants to have his or her research program suspended. It’s far better to have an evaluation done by an accreditor, which can help you improve, rather than start with a government inspection—which could lead to a suspension of the trial.

If your facility is interested in becoming accredited, consider the following pointers suggested by an accreditation expert:

1. Get a copy of the relevant accreditation standards, says Marjorie Speers, PhD, executive director of the Association for Accreditation of Human Research Protection Programs, Inc. (AAHRPP).

Go to www.aahrpp.org/standards.htm to see the AAHRPP standards.

The Partnership for Human Research Protection (PHRP) standards can be found at www.phrp.org.

2. Examine the standards to determine whether your organization would like to seek accreditation. “It is a rigorous set of standards, but they are all achievable,” Speers says.

3. Get a commitment from your institution to pursue accreditation. You may run into problems if your organization doesn’t fully back the idea.

4. Put together a committee with broad representation. Consider including the following:

- Institutional review board members
- An employee involved in education at the facility
- High-level administrators
- Researchers
- Representatives from various units (e.g., medical center, clinical research center, pharmacy, etc.)

High-level administrators are key members of the committee, Speers says. As you go through the standards, you may find resources need to be added in certain areas. High-level administrators can help you get the resources you need to make changes.

5. The committee should meet to go through the standards and pinpoint where changes should be made.
Survey: Of those seeking accreditation, many facilities uncertain about which accredditor to choose

A recent survey shows that 30% of research professionals work in a facility that plans to seek accreditation. However, nearly 50% say their organization remains undecided about whether to seek accreditation for their research program or IRBs.

Of organizations that took the survey offered to Clinical Trials Compliance and Clinical Trials Weekly subscribers, 5% are already accredited. An additional 1% are currently going through the process. Only 16% of respondents say their organizations will not pursue accreditation.

Those who say they will not seek accreditation gave the following reasons for their decision:

- 39% don’t know which of the two accreditors to choose, the Association for the Accreditation of Human Research Protection Programs (AAHRPP) or the Partnership for Human Research Protections (PHRP)
- 25% say accreditation costs too much
- 14% don’t think their organization is ready to meet the standards
- 14% cite that it’s not mandatory
- 6% say they don’t think it’s worthwhile

Of those that do plan to seek accreditation, 49% plan to go through AAHRPP exclusively, 12% plan to go through PHRP, and nearly 40% say plan to go through both.

Timeline
Most organizations say they are not currently going through the accreditation process:

- 54% say they plan to begin the process in the next year or two
- 18% will begin the accreditation process in 3–5 years
- 4% in 5–10 years
- 11% say they would never begin the process

Facts about the survey
This survey was sent to readers of Clinical Trials Compliance and Clinical Trials Weekly. Respondents work in a variety of settings, including:

- 36% in hospital settings
- 19% in academic medical centers
- 13% in physician’s offices
- 12% in private research organizations
- 5% in contract research organizations
- 4% in IRBs

Other locations included the following:

- Pharmaceutical companies
- Biotech companies
- Private companies, clinical-research departments

The most common job titles of the people who took the survey are as follows:

- 25% research administrator/manager
- 21% site coordinator
- 11% compliance officer
- 7% clinical trials compliance officer
- 4% principal investigator
- 4% IRB chairman or member
- 1% chief operating officer

There were a number of clinical-research associates and IRB coordinator/managers who took the survey as well, in addition to several other titles.
In May 2003, the Association for the Accreditation of Human Research Protection Programs (AAHRPP) awarded two organizations with full accreditation status.

The University of Iowa in Iowa City and the Western Institutional Review Board in Olympia, WA, became the first nongovernmental research organizations in the nation to receive accreditation. Representatives from both facilities say their leaders are strong supporters of voluntary accreditation, which is why they moved so quickly to begin the process.

When these organizations chose AAHRPP, the association was the only one offering accreditation to private research organizations. Since that time, the National Committee for Quality Assurance has partnered with the Joint Commission on Accreditation of Healthcare Organizations to form a second accreditation program. (See related story on p. 10.)

“We were eager to have our program reviewed,” says Trish Wasek, CIP, director of the human subjects office at the University of Iowa. “I think for us it was a validation of what we always believed to be very sound practices in human subject protections.”

Angela Bowen, MD, president of the Western Institutional Review Board, believes the accreditation will reflect well on the work the board does. She hopes more organizations will embrace accreditation in the future. “I think it’s a way that you can bring some level of competence to the entire world of IRBs,” she says.

Moving through the accreditation process
Step 1: Self-assessment
The first step in the AAHRPP accreditation process is a self-assessment process, which is submitted as a program description, according to AAHRPP. The two accredited organizations tackled this process in different ways.

- **University of Iowa**—“We were very fortunate because we had just hired a full-time IRB co-chair, Martha Jones,” says Wasek. Jones, who reports directly to the assistant vice president for research, was able to pull together the self-assessment as soon as she began her new position.

  There was no formal committee, but Wasek and others met regularly with Jones as she put the application together, says Wasek.

  “My background is as a research assistant, and this process was similar to putting together a grant application,” she says. “There were other people who had to be consulted, who may have had to contribute small sections of information, and that’s kind of how we approached it.”

  Wasek says it’s hard to know how long it took to complete the self-assessment. “Martha was hired in June, started working on this in June, and submitted it in September. She worked on it in addition to her full-time IRB duties.”

  In total the self-assessment was between 400 and 500 pages long. The bulk of the document consisted of copies of the university’s forms, such as reports, applications forms, and templates used in the office.

- **Western Institutional Review Board**—This organization formed a committee to pull together the application. It began the process last fall, pulling together a team leader and three others. The group worked together to gather all the necessary documents and to write the narrative.

  All in all, the process took about three months, but the
committee only worked on it one or two hours a week, says Bowen.

Western IRB consists of 11 IRB panels and serves as the sole IRB for 83 research institutions, which range from community hospitals to clinics to major academic institutions, such as Johns Hopkins and Boston University. “We have a panel in Santiago, Chile, another in Vancouver, British Columbia, and the remainder are here in Washington State,” says Bowen.

The self-assessment was “quite intensive,” says Bowen. The committee ended up submitting thousands of pages of meeting minutes and protocols. “[AAHRPP representatives] were good auditors,” says Bowen.

Step 2: The site visit

After submitting their self-assessments and documentation, both the Iowa and Washington organizations were able to schedule site visits. At Western Institutional Review Board, the site visit lasted a week. At the University of Iowa, it took three days, which according to Wasek, was probably based on the size of the university’s program.

- **Western Institutional Review Board**—At Western Institutional Review Board, “[AAHRPP] sent six people out . . . and interviewed board members, employees, our clients, our investigators,” says Bowen.

  It was similar to a federal audit visit, says Bowen, but the team was a bit friendlier. “Not that it felt like your best friend came for a visit, but it was very cordial,” she says.

  “After the site visit, they sent us a written summary and we sent them back what we thought might have been misperceptions on a point or two,” says Bowen. Then they waited a response. They were confident “without being cocky” that they would receive full accreditation, she says.

- **University of Iowa**—At the University of Iowa, the site visit was scheduled in January. “I wouldn’t describe it as difficult—it was busy,” says Wasek.

  There were many individual meetings with members of the human subjects office staff. A number of the chairs, co-chairs, and vice-chairs, and probably half of the IRB members were interviewed. Then the team also spoke with other researchers around campus.

  “We told people, ‘be honest, explain what you do, and answer questions the best you can,’ ” Wasek says. “We did have a meeting of the full IRB to explain to them what AAHRPP was—it was a really new body at the time—and give people some background.”

  During the site visit, the audit team also reviewed records. “I wasn’t really surprised along the way, simply because it’s similar to having a site visit after submitting a grant to the National Institutes of Health [NIH] and a team of NIH reviewers comes out to do a site visit,” says Wasek.

Accreditation status

Both organizations say that the process was worth the time and effort. As to whether it will improve their standing among sponsors or subjects, “that’s something we’ll have to see,” says Wasek.

Accreditation is valid for three years and these organizations must now submit annual reports to AAHRPP on the status of their human research protection programs, according to AAHRPP.

Other organizations planning to undergo the process should be certain they are in compliance before moving forward. “I can’t imagine going through such a thorough process if you’re not,” says Bowen. “It would be apparent right away.”

Both organizations say the process was also educational for them. They have made small improvements as a result. “It was a very valuable experience, and as I said, while I believed we had a strong program, I think there is always room for improving the process,” says Wasek.

Go to [www.aahrpp.org](http://www.aahrpp.org) for more information on AAHRPP accreditation.
AAHRPP accreditation: The basics about the program

The Association for the Accreditation of Human Research Protection Programs (AAHRPP), founded in response to the suspension of research programs at major universities, was incorporated as a nonprofit organization in April 2001.

“AAHRPP seeks not only to ensure compliance, but to raise the bar in human-research protection by helping institutions reach performance standards that surpass the threshold of state and federal requirements,” according to a statement on the association’s Web site.

Who is eligible for accreditation?
Any public or private entity engaged in human-subject research is eligible for AAHRPP accreditation. But the organization must have a human-research protection program.

There are seven types of “accreditable” entities, according to the AAHRPP definition:

- **Academic institutions:** Generally, the academic institution would apply for accreditation as a whole unit, regardless of the number of IRBs or separate schools within the university.

- **Hospitals:** The hospital also applies for accreditation as a whole unit, but in large hospital systems, individual hospitals that are “functionally separate and have chief executive officers or directors” can apply separately.

- **Government agencies:** An agency within a department under a director or administrator is eligible for accreditation.

- **Private corporations:** These entities are eligible if they operate under a single chief executive officer.

- **Independent review boards:** They are eligible for accreditation, although institutional review boards (IRBs) that are part of a larger institution cannot be accredited separately.

- **Other entities:** If they have human research protection programs, other entities are eligible for accreditation. Contact AAHRPP for more information.

- **International entities:** These are eligible if they fall into one of the categories above.

How much does accreditation cost?
The following lists the 2004 application fees from the AAHRPP Web site. The fees for accreditation vary depending on the size and complexity of the organization.

- **Level 1** (0–100 protocols, one to two IRBs) $7,700
- **Level 2** (101–500 protocols, one to two IRBs) $12,100
- **Level 3** (501–1,500 protocols, one to two IRBs) $16,500
- **Level 4** (1,501–2,500 protocols, one to two IRBs) $20,900
- **Level 5** (2,501–3,500 protocols, one to two IRBs) $25,300
- **Level 6** (3,501 or more protocols or three or more IRBs) negotiated

Organizations with more than two IRBs will need to pay an additional $3,000 per IRB.

In addition, organizations will be subject to an annual fee, which ranges from $4,160 for a Level 1 program to $10,400 for a Level 5 program. The price of Level 6 programs is negotiated.

In annual fees, organizations with more than two IRBs will pay an additional $1,200 per IRB.
Are there different accreditation categories based on how well the organization performs?
Yes. The accreditation categories are as follows:

**Full accreditation:** These organizations have met all AAHRPP standards and have received accreditation for three years.

**Qualified accreditation:** These organizations meet nearly all the standards, but have received some minor requests for corrective action that are generally administrative. This accreditation is valid for three years. If the outstanding issues are resolved before the next accreditation visit, the organization may be bumped up to full accreditation.

**Accreditation withheld:** These organizations have failed to meet a number of standards. AAHRPP does not believe the organization would or could meet the criteria for qualified or full accreditation at that point. Organizations may reapply for accreditation at their own discretion.

**Accreditation pending:** An organization is placed in this category until AAHRPP decides to award full or qualified accreditation or to withhold accreditation. An organization would be placed in this category, for example, if it does not meet qualified or full accreditation criteria, but AAHRPP believes that it can reach that standard.

Organizations in this category need to submit an improvement plan. This must typically occur three months from the date of the AAHRPP Council on Accreditation decision. All organizations that wish to retain their accreditation status must reapply to AAHRPP before the end of the three-year accreditation period.

**What does the accreditation process involve?**
AAHRPP accreditation includes several steps:

1. **Self-assessment:** Organizations should conduct extensive internal reviews. They must also complete applications and provide full descriptions of their human-research protection program to AAHRPP.

2. **On-site evaluation:** A team of surveyors visits the site to review materials and evaluate the organization’s performance.

3. **Council review:** AAHRPP’s Council on Accreditation reviews information about your organization, including the information from the site visit, and determines accreditation status.

4. **Notification:** Once the council has determined accreditation status, your organization will be notified.

The Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP), has announced a number of new officers who will serve two-year terms. The new president of the board is Barbara Bierer, MD, senior vice president for research at Brigham and Women’s Hospital in Boston.

“"I am a true believer in the importance of accreditation as a means for organizations to demonstrate their commitment to human-research protections, and have proudly served on the AAHRPP board since its inception,” she said in a written release. “For hospitals and academic institutions engaged in clinical research, accreditation has a particularly high value.”

She replaces David Skorton, MD, president of the University of Iowa.

The other new officers are as follows:
- **Vice president—Mark Brenner, PhD,** associate vice president for research, Indiana University and vice chancellor for research and graduate education, Indiana University–Purdue University Indianapolis campus.
- **Secretary (second term)—Steven R. Smith, JD,** president and dean, California Western School of Law.
- **Treasurer—Richard Gelula, MSW,** executive director, National Sleep Foundation.
In January, the Patient Advocacy Council (PAC), an independent IRB in Mobile, AL, became the first organization to receive accreditation from the Partnership for Human Research Protection, Inc. (PHRP).

PAC began the accreditation process nearly two years ago, before PHRP officially released its final standards. “Our company’s culture is such that we are always looking for ways to improve,” says PAC President Karen Pellegrin. “This is an organization that is not afraid to have some external scrutiny.”

PAC, which currently oversees about 150 open studies, chose PHRP accreditation over the Association for the Accreditation of Human Research Protection Programs (AAHRPP) because PHRP is a joint venture between two organizations that have years of experience with accreditation—the Joint Commission for the Accreditation of Healthcare Organization (JCAHO) and the National Committee for Quality Assurance (NCQA). “It was really their reputation that led us to PHRP,” says Pellegrin.

**Beginning the process**

Once PAC decided to seek accreditation, the process began with a thorough review. Pellegrin and Daphne Childers, CCRC, CIM, vice president of operations at PAC, pored through the PHRP standards. Initially, they used the draft standards that were released by PHRP in 2002, and then they reexamined their work when the final standards were issued in 2003.

“If you really walk through each standard and check yourself, it is a very intensive process,” says Pellegrin. It also proved very time consuming.

**Developing action plans**

After reviewing the standards, Pellegrin and Childers (with input from IRB members) came up with action plans to make changes. “I think the biggest area that we have seen benefits . . . has to do with the level of detail with which we now document specific elements of the [IRB] reviews,” says Pellegrin.

In the wake of its self-assessment, PAC developed a series of checklists for board members to use with various studies. Some are general checklists to help board members with new submissions.

Others are designed to address the needs of vulnerable populations, says Pellegrin. Board members are given the appropriate checklists for each study they review.

**Beyond the basics**

The standards issued by PHRP are designed to exceed government regulations, according to Pellegrin. That they do so, she says, helped the organization go beyond the basics and implement what accreditation experts consider to be best practices. “It enabled us to say, ‘Where else can we exceed the minimum requirements of the regulations?’ ” she added.

**Using the online assessment tool**

Once this initial self-assessment was complete and necessary improvements were made, Pellegrin and Childers completed the online assessment tool provided by PHRP. The tool includes a series of questions that must be answered, and it allows the organization to attach documents that are later reviewed off site by PHRP surveyors.

**On-site survey**

Three PHRP surveyors came to PAC in November 2003 to conduct an on-site review. During the visit, surveyors met with Childers and Pellegrin, as well as the IRB chairman and two IRB members. They also reviewed documents during the visit.

“I think what they were looking for, at least from me, was information about what our approach was to human-subject protections,” says Pellegrin. “My preparation to [board members] was just to answer their questions honestly and to provide as much information as possible.”

**Feedback**

PHRP surveyors held a meeting with PAC officials and offered some general comments on the program prior to leaving. The surveyors didn’t issue a score at this
time, but a preliminary score was issued shortly thereafter.

The preliminary score included comments, which PAC was given to review for accuracy. They had the option of submitting rebuttals in areas where they believed information was inaccurate or misleading. Those findings were then reviewed and the final score was issued. In January, PAC received notification that it had been accredited.

PHRP awards either one- or three-year accreditation based on how the organization scores. Because the checklists and many of their other programs were new, PAC received one-year accreditation and is already in the process of preparing for its next survey, according to Pellegrin. “We’re tweaking at this point,” she says.

PHRP accreditation: Questions and answers

These questions were answered by Jennifer Briefer French, assistant vice president of human-research protection at the Partnership for Human Research Protection (PHRP). She spoke during a recent audio-conference sponsored by PHRP, designed to explain the PHRP accreditation process.

Q Is there a minimum number of research protocols that an IRB must review each year to be eligible for accreditation?

A A site must have at least 16 protocols per year in order to seek accreditation. This is the case because our review of protocol files depends on us having a substantial enough number of files to be able to generate a result that has some validity to it. If your organization is too small or has too few active protocols to be eligible for accreditation, you can still use the readiness evaluation tool for as long as you like. If your research program is in a growth stage, it’s a great way to get organized and prepared for accreditation. Once you do have enough volume to support an accreditation survey, we will certainly come out and conduct one at that point.

Q Once an organization is accredited, how long does the initial accreditation last and when is it reviewed again? I’d also like to know what the fee is for renewal.

A The duration of accreditation depends on the organization's score and performance in the accreditation process. Full accreditation is for three years, and it would be granted if the organization receives between 85 and 100 points out of the 100 points available. In that case, the organization would have to go thorough the renewal survey before the expiration of the accreditation. The cost to renew in this case will be the same price as the initial survey.

Organizations that receive a score between 55 and 84 points will be accredited for one year. The renewal price for those organizations is 80% of the full survey amount and would need to take place within the year of the initial review.

Q How often are standards going to be updated? Will the Web tool provided by PHRP automatically be updated to reflect those changes?

A The standards will be reviewed annually and may be updated during each of those reviews. Changes may or may not be made, however. The current standards will be in

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effect until the end of 2005, but new standards will be published at the end of 2004. That gives organizations a full year to review the changes before they must implement them. Smaller revisions to the standards, such as clarifications and corrections, are published quarterly and released in the survey tool. Individuals with hard copies of the standards will also receive updates.

**Q** What would cause an organization to lose its accreditation?

**A** An organization would never automatically lose its accreditation. Its accreditation could expire if it reaches the end of the effective date and does not renew. In addition, the organization could lose accreditation during the current period if the organization has committed fraud in applying for accreditation in the first place. If a significant event occurs—for example, the death of a subject, or if some restriction was imposed on the organization’s insurance—it might also trigger a discretionary survey, which would be conducted to see if the organization still deserves its accredited status. This would be a very thorough review and would be subject to all the due process steps we allow in the standard accreditation process before a decision would be made to revoke accreditation. We expect this process would only be used in the rarest of circumstances.

**Q** We've been in existence as a research department for more than 10 years. I'm wondering how far back would we want to look to review studies that we have already done. Do we just look at studies that we are currently doing and those going forward?

**A** For organizations going through a survey for the first time, we look at current policies and procedures. When we review files, we look as far back as three months, if that’s as far as we need to go back to get our sampling of 16 studies. We may have to go as far back as a year to get those 16 studies. It really depends on the volume of research that you do. We will look only for relatively current studies on the first survey. On the renewal survey and any subsequent survey, we will look back a full year for everything. We look for sustained compliance.

**Q** We do not have our own IRB. We use a central IRB, so we could use 10 IRBs at any one time. How would you handle a review of our operations?

**A** It depends on the situation. If you have a stable relationship with one or more IRBs that review most or all of your research, we could review those IRBs as part of our survey of your organization. If they were already accredited, we would give automatic credit for a majority of the standards we review for each IRB as part of the survey of your organization. If you don’t have a stable relationship with a set of IRBs, the situation changes.

For example, if the sponsor tells you which IRB to use, if it varies from one study to the next, if you can’t predict who you are going to send studies to, and you don’t have a written agreement in place with those IRBs, then you would not be eligible for PHRP accreditation. We’re looking to accredit human research protection programs that are systematic, and that includes what happens within the organization and within the IRB.