IRB ADVISOR

Your Practical Guide To Institutional Review Board Management

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Organization leverages community resources for outreach, education

AAHRPP standard is simple, but directive

Accreditation standards regarding community outreach and education encompass just two short paragraphs and elements in the standards written by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) of Washington, DC.

But this short section is intended to emphasize the importance of the role the public has in supporting research, as well as participating in research, says **Marjorie A. Speers**, PhD, president and chief executive officer of AAHRPP.

"The history of this standard dates back to 10 years ago when AAHRPP was created," Speers says. "In early 2000, an Institute of Medicine report on preserving public trust made a major point that protecting research subjects is a shared responsibility, and it's not just the responsibility of the IRB."

The IOM report made the case that in order for research subjects to be responsible and act responsibly in research, they would need to be educated about more than just the protocol and a particular subject, Speers explains.

"They need to know what research is and what their responsibilities and rights are as research subjects," she adds. "The idea is if we have a public that's well educated and well informed then that research public would be much better at participating in research."

With this report and its findings in mind, AAHRPP developed Standard I-4 to hold research institutions accountable for community outreach and education about the role of research.

All research institutions seeking accreditation must demonstrate their commitment to public outreach and education, but for most this activity might have a limited role in their overall work and standard operating procedures.

But at least one institution has found that community outreach and engagement is important to their overall mission.

"We formed relationships with various community partners," says **Michael Briggs**, chief administrative officer for the University of New

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Mexico Health Science Center (UNMHSC), Clinical and Translational Science Center (CTSC), of Albuquerque.

"One of the challenges in New Mexico is that we are such a broad, vast state with a very disparate population," Briggs explains. "We only have a population of about two million, but it's such a large state — the fifth largest in the union — and Albuquerque is right in the center, so we outreach to all four corners of the state."

Bridging the geographic differences required collaboration and partnerships.

"So once we formed our CTSC, we tried to help our community members obtain access to a centralized IRB office," he adds. "We opened our institutional review board at the health sciences center to our partners throughout the state and community."

The UNMHSC CTSC took these major actions with the goal of enhancing its community presence:

- Officials met with more than 40 organizations spread across the large but sparsely populated state and engaged with them to serve as their IRB. The participating IRBs include 16 of the state's 19 Pueblos;[1]
- The institution established enhanced IRB training, implementing modules that are integrated into Human Research Subject Training and using extended modules targeting community researchers;[1]
- They leveraged community resources and collaborated with Health Extension Rural Offices (HEROs) to have the local providers and health care practitioners educate their patient populations about research and particular research studies;[1]
- The institution formed a confederated IRB that includes New Mexico, Colorado, and Utah. The regional CTSA-driven IRB has led to streamlined approval processes for multisite trials.[1]

"We built collaborative relationships with the offices," Briggs says. "The HEROs are in the communities and provide a connection to UNMHSC, and we provide feedback to the community with those community partners."

UNMHSC has taken responsibility for public outreach activities and engaging the public, both of which are part of AAHRPP's goals for research institutions, Speers says.

"When we first started accrediting research institutions, these standards made institutions a little nervous, mostly because they weren't sure what they were supposed to be doing," she explains. "Over time, they'd put something on their website or refer to other websites; some would have brochures in multiple languages; they would have speaker bureaus so people could go out in the community and talk about research and what it means to be in a research study; there are a number of things they could do to meet that standard."

UNMHSC has focused on training HEROs and routinely networking with HERO organizations.

"We bring them in, and they meet with us and we also have networking and training opportunities for

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them," Briggs says.

"The meetings are one-day events where they can meet with our faculty," he adds. "We want them to help us identify what health disparities are in their communities and, hopefully, link them with a researcher or research project that they would be interested in implementing in their area."

For example, some research has noted increased asthma in southern New Mexico, and so HEROs in that region might decide to participate in a study that looks at that problem, he says.

"They would try to recruit participants for a particular study," Briggs says. "They'd ask their patients, 'Since you are an asthma sufferer, would you be interested in participating in this study?' Then we'd train the practitioners on the consent process and data collection."

Also there would be community specialists from the CTSA who would work with the partners to assist them with their clinical trial.

Other outreach strategies include brochures about both specific studies and research in general.

"We work to design the brochures with the HEROs," Briggs says. "And we are in the process now of having a community page put on our CTSC webpage to discuss some of the community resources and to show a map of the different studies available throughout the state."

REFERENCE

1. Newman S, Byram JK, Briggs M, et al. Creating a statewide and regional internal review board to facilitate community-UNM Health Sciences Center engagement. Abstract presented at AAHRPP Conference in Denver, CO: April 18, 2012. ■

What precisely does the AAHRPP community outreach standard say?

Here is Standard I-4, in a nutshell

The Association for the Accreditation of Human Research Protection Programs (AAHRPP) of Washington, DC, has this section devoted to communication with research participants and community outreach in its accreditation standards:

AAHRPP Accreditation Standards: Domain I: Organization

STANDARD I-4: The Organization responds to the concerns of research participants.

Element I.4.A. The Organization has and follows written policies and procedures that establish a safe, confidential, and reliable channel for current, prospective, or past research participants or their designated representatives that permits them to discuss problems, concerns, and questions; obtain information; or offer input with an informed individual who is unaffiliated with the specific research protocol or plan.

Element I.4.B. The Organization conducts activities designed to enhance understanding of human research by participants, prospective participants, or their communities, when appropriate. These activities are evaluated on a regular basis for improvement.

Element I.4.C. The Organization promotes the involvement of community members, when appropriate, in the design and implementation of research and the dissemination of results. ■

BEST PRACTICES SPOTLIGHT

Best practices help new IRB with accreditation

Use of IRB tools helps with success

Within one year of opening its doors in 2009, Opus IRB of Roswell, GA, had its first research review, and within the last year the independent IRB achieved full accreditation from the Association for the Accreditation of Human Research Protection Programs (AAHRPP) of Washington, DC.

Two chief keys to the IRB's success are that Opus IRB developed and improved its comprehensive standard operating procedures (SOPs) and keeps tracking logs and performance metrics, says **Judy Cherry**, RN, CCRC, CIP, administrative director of Opus IRB.

"Our IRB is an independent, central IRB that was formed by a group of individuals that together have more than 50 years of experience," Cherry says.

"Opus IRB's mission is to ensure that research is conducted ethically and protect the safety and well-being of human participants.

"The IRB's founders have watched the research regulatory process evolve over many years, so when they started their own IRB they immediately decided to achieve the industry's highest quality standard through accreditation," she adds.

The Opus board is comprised of specialties from around the nation, providing a national research perspective and expertise, she says.

"Accrediting early in the game is very unusual, but there was no reason not to," Cherry says. "Since we were developing an IRB we just looked at this as if it was really important to ensure we had everything in place."

Here are some of the best practices, Opus IRB followed:

1. Create a comprehensive set of SOPs.

"The first thing we tackled was the SOPs because our SOPs tell the whole story of the organization," Cherry says. "We made sure all of the regulations were covered."

Also, the SOPs include references and links. So at the place where the SOPs discuss waivers of consent, there is a checklist available to see if the protocol is eligible for a waiver.

During the accreditation process, AAHRPP reviewed the SOPs and made suggestions for changes. For instance, AAHRPP suggested Opus IRB provide greater details about its community outreach program, noting what the IRB staff and board were doing with regard to teaching and speaking to the public about research and human subjects protection, Cherry says.

2. Emphasize checklists and links to tools.

Opus IRB provides a public list of 11 IRB forms and tools, in PDF format, on its website at www.opusirb.org. These are continually being revised and improved, Cherry says.

"We opened them to the public so when investigators are looking at Opus IRB they can look at the forms and know what will be required of them," she says.

Included among the forms is a final closeout report that includes a list of closeout activities with space to add information, such as the date when these occurred. These activities include:

— date of study closure at site;

— date last subject completed study (including all follow-up visits/phone calls);

— total number of subjects consented;

— total number of screen failures;

— total number of subjects completing study;

— total number of subjects withdrawn/early terminated from study.

The final closeout form also has "yes" and "no" check boxes for specific and important questions, including these:

— Have there been any significant protocol deviations that have not previously been reported to Opus IRB?

— Have there been any unanticipated problems involving risks to subjects that have not previously been reported to Opus IRB?

— Have there been any serious adverse events that have not previously been reported to Opus IRB?

— Has the site been audited by the FDA or OHRP since your last report?

A final section on the closeout form relates to audit information. It is completed only if the site has been audited by the Food and Drug Administration.

3. Use tracking logs to collect metrics and generate reports.

AAHRPP and potential clients require reports, and one of the best ways to generate these is by using tracking logs for metrics and data, Cherry suggests.

Tracking logs keep all of the necessary information immediately available. So if a pharmaceutical company is considering having Opus IRB serve as its central IRB for a multisite study, then Cherry quickly can provide the company with performance metrics, including information about the IRB's turnaround time and how far in advance a protocol review needs to be scheduled to be put on the IRB's calendar.

"They're very interested in those things," she says. "Time is money for them, and we always have the information at our fingertips."

The information is useful for making sure investigators have submitted all the necessary credentials, as well.

"We don't need to ask for a signed curriculum vitae or medical license for every single study when an investigator has several studies that have been reviewed," Cherry explains.

The database will let the IRB office know when an investigator's CV on file needs to be updated or when a license is about to expire. It also keeps track of all study amendments so these can be pulled up at the time of the continuing review, she adds.

"The tracking log allows for us to create the annual AAHRPP report quickly," Cherry says. "It is a working document; we don't have to go through every study to find the information." ■

Mentoring can improve human subject protection

Training geared toward students, residents

Physicians often are engaged in a research study at some point in their careers, but if they're working in the community primarily as clinicians they might not receive optimal mentoring and training in protecting human research subjects.

Problems occur when new student researchers start their first research project without having full knowledge of the human research subject protection and other regulations, says **Barbara Frentzen**, ARNP, MSN, coordinator of clinical programs, department of neurosurgery, University of Florida in Gainesville. Frentzen is the principal author of a study about the department's mentoring and educational program for new researchers.

"They can become frustrated and start to hate the difficult process of research if they don't have people who help them through it initially," Frentzen says.

The solution is to develop a program that provides medical residents with specific training through the IRB and through faculty mentoring. The University of Florida's department of neurosurgery began to implement a more formal training process five years ago with a research ethics educational series.

"The chairman of the IRB speaks about the role of the IRB," Frentzen says.

Also, a medical ethicist spoke with residents about research ethics, and the head of the IRB office provided a nuts-and-bolts educational session on the IRB submission process, she adds.

Among the topics presented in the series were:

— the history of research ethics;

— the institutional review board;

— federal regulations;

— informed consent;

— the Health Insurance Portability & Accountability Act (HIPAA);

— the ethics of writing for publication.

"I talked about the best strategies for interacting with patients to obtain informed consent," Frentzen says. "Our general counsel talked about what to do when a patient cannot consent for himself."

Since all residents are required to conduct one research project per year, educational lectures and sessions are important to their development as researchers. Fledgling researchers also need an opportunity to obtain expert feedback on their research proposals.

"Residents understood they could not start a project or collect data without IRB approval," Frentzen said. "For the next step, we created a research review committee."

The departmental research committee, consisting of the departmental chair, a younger faculty member, a statistician, and the resident who won the previous year's research award, reviews written proposals and provides feedback.

"We send comments back to each of the residents about the strengths and weaknesses of each proposal," Frentzen says.

Residents amend their projects and present the revised proposals to faculty and fellow residents for additional comments and feedback.

"Proposals are reviewed twice, and we think that will help improve the quality," Frentzen said.

Frentzen created a written research proposal template that residents can use. It includes at the top the date the written proposal is due and the date of the oral presentation to neurosurgery faculty, as well as the researcher's name, project title, and mentor's name.

Other features of the template are as follows:

- abstract: a summary of the proposed study in 250 words or less;
- hypothesis and specific aims;
- background and significance;
- preliminary results;
- research plan and methods.

The template advises researchers to have their mentors approve it before they send it to the department research committee and that they then should begin preparing their IRB and HIPAA submissions.

The final page of the template includes a timeline of activities that should be done with columns for putting dates at the targeted date of completion and the actual date of completion.

This process has led to a much more efficient and faster IRB review process for resident researchers, Frentzen notes.

Since the IRB review is faster, residents have more time to collect and analyze data. As a result, the number of published studies among residents has increased in recent years, Frentzen adds.

"The number of times residents were first authors on their first publications went up significantly, as well," she says. "They were owning what they did much more than in previous years, and it was very exciting."

The mentoring program has been another way

to ensure resident researchers are complying with research regulations and maintaining high ethical and professional standards.

"Each student picks a faculty mentor," Frentzen says. "Prior to sending the proposal to the research committee, they meet with their mentor."

They discuss their research idea with the mentor and determine ways to improve the proposal. Mentors can help new researchers with design and analysis of the study.

"They need mentoring both in terms of how to design a study, clarify a question, and determine what is really relevant in terms of their professional development, and they need people who help them get through the nuts and bolts of the regulatory process," Frentzen says.

Once a new researcher is prepared to start the trial, he or she submits an application to the IRB, which Frentzen reviews.

"We go through the IRB process, which involves a review by their office staff to make sure everything is complete, and then the IRB chair reviews everything," she explains. "I sit with the chair to answer any questions he might have."

All of the additional training, mentoring, and reviews have improved the research process, making it less frustrating for new investigators, Frentzen says.

"Making the process smoother for them will contribute to making them more willing to be involved in research," she says. ■

Waiting on the ANPRM, IRBs continue innovating

Some IRBs plan to reduce burden

More than a year after the Department of Health and Human Services released its proposed rewrite of the Common Rule, researchers and IRBs still are waiting for the other shoe to drop.

The advance notice of proposed rule-making (ANPRM) recommends sweeping changes to the ways in which IRBs and researchers protect human subjects — from risk assignment to protecting personal information to handling multisite review.

It prompted an avalanche of comments, more than 1,100 on virtually every aspect of the proposal. But since the comment period closed in late October, things have been quiet at HHS. There's no word on when — or if — the ANPRM will advance to its next step, a notice of proposed rule-making, let alone to an eventual final rule.

In the meantime, IRBs are left to wonder what they should do. Sit tight and wait to see what happens? Forge ahead with quality improvement efforts? Innovate, as many institutions already have, using the flexibility in the existing federal regulations?

Those who have been watching the process say institutions would be wise to proceed as though there is no ANPRM, since any final outcome of a Common Rule rewrite could be far off, and extremely uncertain.

"I generally advise people not to worry about the ANPRM," says **Jeffrey Cooper**, MD, MMM, of Huron Consulting Group in Arlington, VA. Cooper advises IRBs about ways to improve their operations.

"What eventually comes out could be nothing like what was suggested," he says. "I think predicting the ANPRM is harder than predicting the presidential election after this presidential election."

Inter-agency concerns and politics

HHS spokeswoman **Ann Bradley** says the department is still weighing how the public comments will be incorporated into any notice of proposed rule-making.

"We do not, to my knowledge, have a timetable for next steps," she says.

Cooper notes that the huge number of comments generated by this proposal will take a while to sort out. And Cooper says that the process going forward will have to involve a number of other federal agencies who abide by the Common Rule — everyone from the Department of Energy to Veterans Affairs and the Department of Defense.

"If you look at DOD regulations, for example, or you look at VA regulations, you would find a set of regulations that mirror the wording that's in 45 CFR 46, so their regulations would have to change as well," Cooper says.

Getting all of those different agencies to sign off on the changes is not an easy or speedy process, he says.

"There was an inaccurate footnote in the Common Rule when Subpart B was changed for pregnant women," Cooper says. "It was a footnote on the exemption rules and it took about five years to get that taken off."

Politics also may come into play, say Cooper and **Moira Keane**, MA, CIP, who retired this summer as director of the University of Minnesota's Human Research Protection Program in Minneapolis. A presidential election could change the playing field in Washington, as well as the direction in which HHS plans to go.

"It wouldn't surprise me if they decided to just let it sit until things are sorted out in terms of elections and a cabinet, and if there are changes at HHS, who knows?" Keane says. "I would actually be surprised if something happened between now and November."

Keane is also among those advising IRBs not to make any big plans based on what's in the ANPRM. At the same time, she says institutions that are planning their own improvements or innovations shouldn't table them to see what happens with the federal regulations.

Among those taking that advice is the University of Southern California in Los Angeles. **Susan Rose**, PhD, executive director of USC's Office for the Protection of Research Subjects, has been leading a group of institutions in what they call the Flexibility Coalition, searching for ways to use the flexibility in the existing federal regulations to alleviate burdens on IRBs and researchers while better protecting subjects.

One tool these organizations have used is "unchecking the box" on their Federalwide Assurance (FWA), so that they are not required to apply every aspect of the federal regulations to every study, regardless of funding source.

The unchecking advantage

For example, an organization that doesn't check the box would not be required to extend Subpart B to minimal risk surveys of pregnant women as long as the research isn't federally funded. Proponents of unchecking note that the federal regulations make it difficult to do even minimal-risk social and behavioral research with pregnant women because of Subpart B's requirement that the research either directly benefit the woman or fetus or contribute to the development of "important biomedical knowledge."

"Subpart B is essentially written to pretty much exclude the possibility of doing non-biomedical research with pregnant women," Cooper says. "So if you uncheck the box, and you have research that involves no more than minimal risk to the subject and the subject's pregnancy, don't apply Subpart B."

Rose says her group is continuing to pursue these types of initiatives, even though one ANPRM proposal would extend federal regulatory protections to all research, regardless of funding — essentially eliminating the unchecking advantage.

She and others want to retain this flexibility in the federal regulations, saying it allows institutions to better calibrate the level of review to the actual risks in studies. Rose says she hopes that the lack of an immediate notice of proposed rule-making is a sign that HHS is taking the objections raised by commenters seriously.

"Everybody is enjoying the silence, hoping that it means the feds are reflecting on how very thoughtful the comments were," Rose says. "If they had rushed out with something, it would be a sign that they weren't listening."

Another institution using unchecking is the Children's Hospital of Philadelphia. **Mark Schreiner**, MD, chairman of the Committee for the Protection of Human Subjects at CHOP, says officials at his institution actually unchecked the box after the ANPRM was released, in part to deal with expedited review categories that they found to be too constraining.

"We had several conversations with [the Office for Human Research Protections] and they said, 'We're working on a revision,'" Schreiner says. "So we didn't do anything. And when we saw the proposed rule, we said 'OK, we're just going to act.'"

And what happens if an eventual final rule removes this possibility?

Schreiner says he's not worrying about that now.

"We don't operate based on rumors; we operate based on what's real and here right now." ■

Take steps now to reduce burden

IRBs can improve without new regulations

As institutions wait to find out what comes out of the ANPRM, there are steps they can take now to work within the current regulations and achieve the Department of Health and Human Service's goals of lessening the burden on investigators and IRBs while still protecting subjects.

Jeffrey Cooper, who consults with institutions

about improving their human subjects protection programs, says IRBs should look for ways to use exemption determinations and expedited review whenever possible for research that either doesn't involve human subjects or involves only minimal risk to subjects.

"People who do minimal-risk research, social and behavioral research, often feel that IRBs are over-regulating their research," says Cooper, MD, MMM, of Huron Consulting Group in Arlington, VA.

"If you look at the regulations, it's really quite easy to protect subjects in that kind of research by following the requirements of the regulations and that's it."

"You want to have a rational approach to risk assessment so that you can accurately determine whether risks are, in fact, minimal."

In addition to recommending that institutions uncheck the box on their Federalwide Assurances (see accompanying story, page 102), Cooper proposes waiving the requirement for written documentation of consent in most minimal-risk research. Cooper argues that it is usually unnecessary, and often an impediment to research, especially social-behavioral research in other cultures that view written documents differently than Americans do.

"You still need to talk to people, you still need to get their permission, but you don't need to get a signature from them on a piece of paper," he says. "That can be done on all research that involves minimal risk in which there's not some legal requirement outside the context of research to get written documentation of informed consent."

Cooper believes this approach can actually be more protective of subjects, as investigators focus more fully on the process of consent, rather than simply getting a signature on a piece of paper.

"Some investigators have told me, 'Now, I'm going to have to sit down with them, make sure they really understand what they're getting into, before I let them agree to take part in the study,'" he says.

He says the ANPRM doesn't really address the process of consent, focusing mostly on documentation issues.

"They talked about shortening the number of pages or having templates for what the paper should look like," Cooper says. "It was all about the paper and not about conversations between investigators and subjects."

Consistent decisions about minimal risk

Similar efforts to lessen regulatory burden are under way at Children's Hospital of Philadelphia, says **Mark Schreiner**, MD, chairman of the Committee for the Protection of Human Subjects.

Schreiner says his institution has determined that many categories of research are always minimal risk, even though they currently aren't in the expedited review categories.

For example, he says, his board has looked at some of the restrictions on blood draws and other procedures and found them to be excessive. So they've adopted limits they believe are more reasonable and if those are met, consider them to be minimal risk.

"For example, low doses of radiation we find to be minimal risk, all the time," Schreiner says. "A lot of studies go to full board just because there's a DXA [dual-energy X-ray absorptiometry] scan, which is a very low level of radiation. It's a fraction of a chest X-ray."

By making these consistent decisions about minimal-risk research, he says, "we think we can reduce the number of items that have to go to the full board, so we can focus on studies that have real risks and require expertise."

Magnitude vs. probability

Cooper says the ANPRM didn't address one problem he sees with risk assessment by IRBs. In his experience, he says, IRBs are good at determining the potential magnitude of a particular risk, but not the probability of it.

For example, he says an IRB might look at the potential for sharing of personal health data, seeing great danger in a laptop being breached, and require stringent security measures for that laptop.

"They'll say, not only do you have to lock your laptop in your office, but you have to lock it in your filing cabinet in your office," Cooper says. "And I'll say, 'Is the laptop encrypted? Because if the laptop is encrypted, you theoretically could leave it in the cafeteria and it would not be a risk.'

"What is the probability that an office will get broken into? What is the probability that someone will be able to read the information off the laptop and disseminate it in a way that will be bad?"

He encourages IRBs to really investigate the probabilities of risks: How many offices have

been broken into at their institution? How many laptops stolen?

"There are things you can do to get some information to help you determine that, and that can be compared against the probability and magnitude in daily life."

Cooper says that when IRBs do that kind of risk assessment homework, they start to focus more on the real risks to participants. "And sometimes, they realize that things they didn't care about are truly a risk and need more [protection] than what they were thinking about." ■

Professionalizing the IRB: One institution's plan

Hospital improves consistency of review

Like many other institutions, the Children's Hospital of Philadelphia often struggled to get and keep good IRB members. Its roster was full of busy physicians who couldn't make all the meetings, and some had to rotate off the board because of the demands of their work.

"To staff our three committees and ensure enough physicians would come, we wound up with committees that were 15 or 17 members," says **Mark Schreiner**, MD, chairman of the Committee for the Protection of Human Subjects at CHOP. "Often, we would just barely make quorum — we would have eight or nine people at a meeting.

"And the problem was that we needed to have a lot of physician members to ensure that we had three or four who were capable of reviewing new material."

CHOP's solution? They cut the number of boards to one, with 11 members and 11 alternates. And to ensure that those members would be there, the CHOP Research Institute pays for the members the equivalent of two days of salary support per month to compensate for their time and effort.

Each member is paired with a particular alternate. Someone from that pair is expected to attend 20 of the board's 24 scheduled meetings each year.

"If they don't make all the meetings, meet their quota, there's no pay," Schreiner says.

It's part of CHOP's initiative to "professionalize" the IRB, ensuring that the work members do part time for the IRB is valued by the members and their department heads.

To pay for it, the institution is using money paid by industry sponsors for protocol review.

Previously, "we hadn't looked at how much money was being generated from industry-related work — it was just going into the research institute, but it wasn't really coming back to the IRB," Schreiner says.

In addition, he says, the institution found it wasn't billing industry for all of the work it had been doing. Initial fees were being charged, but CHOP was often failing to bill for continuing reviews and amendments, which were in the industry contracts.

Valuing the IRB

One goal of this approach is to have department heads and division chiefs see IRB service as valued, since they're the ones who must give the members non-clinical time to serve.

"Often, department chairs provide individuals who have time available, but they're often not people who are engaged in research," he says. "To get specialty expertise but not research expertise doesn't help the committee. And then other people who are busy researchers and who don't have time don't help either."

To form the new, smaller board, Schreiner picked the best members from his three previous boards, as well as a few members who had left the IRB because of time constraints.

"From the three boards, we were able to identify individuals who we thought were good members but also who represented the diversity that we needed to make decisions."

Community members were not left out of the initiative. They are paid a stipend for their work on the board.

"When I joined the committee, our community members were largely elderly people who were retired — they were the people who had time," he said. "They didn't really represent the community we served. We've made an effort over the last five years to get younger people, a little more diverse, people with training in medical ethics.

"The problem with younger people is that they're working and they have to rearrange their time. So a lot of our community members would last with us only a year or so. They'll get a stipend, to help make it possible for them to serve and compensate them somewhat for their time."

High expectations

For Schreiner, professionalizing the IRB isn't just about paying members, but raising expectations. In order to make meetings go more smoothly, board members are expected to be familiar with all of the protocols, not just the ones for which they were the primary reviewer.

"One of the things that can take a lot of time at a meeting is for the primary reviewer to go through the protocol in laborious detail," he says. "Well, our assumption is that everybody will be familiar with every study, so we can focus on the issues."

His office also is taking other steps to reduce unnecessary work for the full board, engaging in cooperative IRB review and making use of flexibility in the regulations to exempt or expedite reviews. When membership on a board is consistent, the same types of studies are likely to be handled in the same way each time, without having to continually revisit issues, saving work for the board and hassle for investigators.

Schreiner says staffing in this department hasn't changed. He will run one of the monthly IRB meetings, while his vice-chair, Barbara Engel, will lead the other.

The new system has only been in place a few months. The first meeting in the new format was July 1.

"The first meeting was efficient, and took less time than many," he says.

And he's already seen one positive effect of the change.

"As soon as there was salary support for the time, we had one department that was proposing additional members," he says. "Instead of begging for members, we're going to be able to choose people who are really good."

Schreiner says the biggest obstacle to a change of this kind is getting the money to fund it. In his case, he went to the director of his research institute to propose the new arrangement.

"We wanted to fund people for two days a month, but you could fund people for part of their time," he says. "Maybe you could only be able to afford to fund them for the equivalent of one day a month."

The ultimate goal is an IRB that holds together over time and can reach consistent decisions, he says. "The only way to do that is to have the same people come each month and do it for a period of time." ■

Little research done for low literacy and consent

Researcher argues that more studies are needed

While many IRBs complain about the quality of informed consent, there's been little substantive research into how to improve it, particularly for subjects with low literacy, says a researcher who has studied the issue.

Leonardo Tamariz, MD, MPH, associate professor of medicine at the University of Miami in Coral Gables, FL, says he and his colleagues found only a half dozen studies that tested an informed consent change to see if it improved comprehension in a low-literacy population.

"And of those six studies, none of them were specifically dedicated to patients with low literacy — they looked at a mixture of patients," Tamariz says. "I don't think many people are working on this, despite this being a big problem. The reason might be because there's not much funding out there to help start those studies."

His group's results were published recently in the *Journal of General Internal Medicine*.[1]

Of the studies his group looked at, only one was randomized and three did not look at informed consent in real research studies, but relied on hypothetical consents.

But even from this small group of imperfect studies, Tamariz says there were some useful insights.

Two of the more successful studies relied on so-called "teach-back" methods, in which a participant is required to verbalize his or her understanding of the informed consent information after receiving it.

"When an interviewer says something, the people being interviewed have to recall what was said in their own words — that's the purpose of teach-back," Tamariz says.

In one of those studies, an interviewer used a script to explain the consent and HIPAA privacy document for a medication adherence study and then had participants respond with information about study design, randomization, and disclosure of data. That study reported a comprehension level of 31% after one round of teach-back.

Teach to goal

The second study used a "teach-to-goal" method — several rounds of teach-back for the same participant — for the informed consent of an advance directive study.

"Teach-to-goal is doing [teach-back] multiple times — if they don't get it the first time, doing it a second time, doing it a third time or a fourth time or a fifth time or a sixth time, so you have a goal of making sure of comprehension," Tamariz says.

First, participants read along with a staff member, then they had to show their understanding of the tasks they'd be encountering in the study. The "first pass" comprehension level of participants was 33% — after three rounds, the comprehension level of those with marginal and inadequate health literacy was 90%.[1]

Tamariz's group notes that the best results came from a study team member speaking with a participant one-to-one. But he says there needs to be more research into this topic, asking participants themselves about what works.

He's currently planning a study that would ask participants who have gone through a consent process about their experience.

"We tend to do things — we physicians or regulators — without asking the key player in the informed consent process, the patient, so that they could give us some answers," Tamariz says. "So I'm planning a study asking what they feel we should do differently, incorporating all of those comments into a teach-back method and then trying to test it and see if that increases comprehension."

IRB interventions

Tamariz's interest in improving informed consent comes from his own experiences, both as a researcher and as IRB chair for Miami Veterans Affairs. In quizzing his own study participants, he learned that many didn't understand basic concepts such as voluntariness.

And he says his IRB routinely receives informed consent documents that are too long and complicated.

"[Participants] need to discuss the consent in its entirety and they need to be able to comprehend it," he says. "When you have a consent that's 25 pages, it's impossible to do. What I'm seeing right now is the consents that are coming from pharmaceutical studies that are sponsored by pharmaceutical companies, those consents are 25-30 pages long. We cannot work with that."

His IRB has sponsored educational sessions for research assistants and principal investigators ("From experience, I can tell you that we had a room full of research assistants and maybe two PIs"). They went through a mock consent process with the audience and showed them how the teach-back method works.

He says he'd also like to see more harmonization among the federal agencies — many of his studies must conform to informed consent requirements from the Office for Human Research Protections,

CNE/CME OBJECTIVES & INSTRUCTIONS

The CNE/CME objectives for IRB Advisor are to help physicians and nurses be able to:

- establish clinical trial programs using accepted ethical principles for human subject protection;
- apply the mandated regulatory safeguards for patient recruitment, follow-up and reporting of findings for human subject research;
- comply with the necessary educational requirements regarding informed consent and human subject research.

Physicians and nurses participate in this continuing education program and earn credit for this activity by following these instructions.

1. Read and study the activity, using the provided references for further research.
2. Log on to www.cmecity.com to take a post-test; tests can be taken after each issue or collectively at the end of the semester. First-time users will have to register on the site using the 8-digit subscriber number printed on their mailing label, invoice or renewal notice.
3. Pass the online tests with a score of 100%; you will be allowed to answer the questions as many times as needed to achieve a score of 100%.
4. After successfully completing the last test of the semester, your browser will be automatically directed to the activity evaluation form, which you will submit online.
5. Once the completed evaluation is received, a credit letter will be e-mailed to you instantly. ■

COMING IN FUTURE MONTHS

- IRB and institution make ethics code a chief priority
- Education program has long reach in research community
- Analyst describes ways to improve IC process
- Using research protocols to expand newborn screening
- IRB communication with researchers: Not just what to say, but how you say it

the Food and Drug Administration and Veterans Affairs.

"We're dealing with three layers and some of those layers are different, so you have to have a longer, more difficult consent," he says. "I think we have to get everyone together — FDA, OHRP, VA, IRBs — in a room and come up with a way that we can trim this down."

REFERENCE

1. Tamariz L, Palacio A, Robert M, et al. Improving the Informed Consent Process for Research Subjects with Low Literacy: A Systematic Review. *J Gen Intern Med*. 2012 Jul 11 (Epub) ■

CNE/CME QUESTIONS

1. The Association for the Accreditation of Human Research Protection Programs (AAHRPP) of Washington, DC created Standard I-4 for which purpose?
   A. To reduce medical and research errors
   B. To ensure adequate research staff training
   C. To make certain subjects know what research is and what their responsibilities and rights are and to contribute to a well-educated and informed research public
   D. All of the above

2. A final close-out report should include all except which of the following?
   A. Date of study closure at site
   B. Date last subject completed study
   C. Total number of subjects consented
   D. All of the above should be included

3. The Department of Health and Human Service's advance notice of proposed rulemaking (ANPRM) would allow institutions to "uncheck the box" on their Federalwide Assurances so that they would not have to apply federal regulations to all research regardless of funding.
   A. True
   B. False

4. Which intervention did the best job of improving informed consent comprehension?
   A. Lowering the reading level of the informed consent document
   B. Using an interactive computer program to explain the consent
   C. Teach-back methods that require subjects to explain what they know