IRB ADVISOR

Your Practical Guide To Institutional Review Board Management

AHC Media LLC

IN THIS ISSUE

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Kentucky IRB office has mentoring program and other education strategies

Information on-demand helps with training

IRB members often begin their new role with many questions and concerns. While these may be answered during a formal training program, there is another way to help ease new members into the role, and that's through a formal mentoring program.

"If you're coming in as a new IRB member, we have a series of training sessions for you, but in addition we will contact another IRB member who is experienced and ask if this person will be the new member's mentor," says **Ada Sue Selwitz**, MA, director of the Office of Research Integrity at the University of Kentucky in Lexington, KY. Selwitz also is an adjunct professor in the College of Medicine.

The institution recently received full accreditation from the Association for the Accreditation of Human Research Protection Programs (AAHRPP) in Washington, DC.

When AAHRPP officials visited the office, they complimented the mentoring program, Selwitz notes.

The institution has four medical IRBs and one non-medical IRB, all with more than 10 members and alternates, says **Helene Lake-Bullock**, PhD, JD, a research compliance officer in the Office of Research Integrity.

Several years ago, when Selwitz and Lake-Bullock began working on improving training and education for IRB members, they checked with 10-15 other institutions to see how they educated their IRB members.

"One of them had a mentoring program in the past, but they had not continued it," Lake-Bullock recalls. "But when I talked to people about IRB member education, they thought it was a great idea to provide mentoring."

The institution's IRB members also liked the idea and said their own transitions might have been easier if they had been mentored, she recalls.

"They were happy to do that for new members," Lake-Bullock says.

The institution also provides updated education and training for IRB members through what amounts to information on-demand.

For example, when a protocol is submitted that involves a vulnerable population, such as children, the IRB office will send IRB members a set of materials that addresses the ethical review of studies involving children, Selwitz says.

"One thing I believe is that adult learners learn best by doing," Selwitz says. "So one thing we do here is if we receive a protocol that requires raising issues either because of ethical concerns or regulatory ones, then we have a set of materials that helps users address those issues."

The office sends IRB members the additional material in their protocol packets, calling this protocol-specific training.

"If I attach those materials to a protocol you're reviewing, then you're more likely to read them then," Selwitz says. "That's a very effective tool."

The additional information is sent to IRB members, but it is shared with investigators when they request more information, Selwitz notes.

"If investigators come to me and say, 'What kind of questions might the IRB raise?' we'll say, 'Why don't you look at what we'll be sending the IRB members,'" Selwitz says.

With experience, IRB members eventually may not need to read the packets of information. But at the beginning this is the second part of their additional training. Mentoring has become a major part of their initial training.

Matching members with similar backgrounds

Because the university has five IRBs, there is continuous turnover and mentoring of new members, but most of the changes occur in the fall, Lake-Bullock says.

"When we get our new assignments in the fall, I set up the mentoring pairs," Lake-Bullock says. "I call on seasoned members and usually try to match them with new members who have the same background."

For example, a medical IRB member will mentor a new medical IRB member, and if someone has a specialty in pediatrics, he or she might be paired with someone else who has that specialty, she explains.

"I've come to find that's pretty important," Lake-Bullock says. "They'd rather be paired with another community member if they're a community member."

Even the IRB alternates are provided with mentoring since they will need to be ready to step into the IRB role when needed, she says.

Mentors are asked to provide assistance to new members for at least a few months. If they feel they cannot handle the time commitment, they can pass and volunteer to mentor later.

"They make a phone call to the new member and introduce themselves and accompany the new member to a meeting," she says. "The mentor will introduce the new member at the meeting and try to make the person feel comfortable."

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For recent permission, please contact: Stephen Vance, *Telephone:* (800) 688-2421, ext. 5511
• *Fax:* (800) 284-3291 • *E-mail:* stephen.vance@ahcmedia.com
• *Address:* 3525 Piedmont Road, Building 6, Suite 400, Atlanta, GA 30305

Editors: **Suzanne Koziatek** and **Melinda Young**.
Senior Vice President/Group Publisher: **Brenda Mooney**, (404) 262-5403, (brenda.mooney@ahcmedia.com).
Associate Publisher: **Lee Landenberger**, (lee.landenberger@ahcmedia.com).
Managing Editor: **Paula Cousins**, (816) 237-1833, (paula.cousins@ahcmedia.com).

Editorial Questions

Questions or comments?
Call **Paula Cousins** at (816) 237-1833.

Once the IRB office decided to start the mentoring program, Selwitz and Lake-Bullock came up with guidelines.

"So we started developing the outline of what we would expect them to do," Lake-Bullock says.

The result is a three-page tool that includes a checklist for the mentor **(see box for sample items from the Welcome Checklist)**.

Lake-Bullock is available if the mentors or new IRB members have any questions once they've been paired, but she says there have been few issues arise.

"It's been very low maintenance," she says. "Once the mentoring pairs are set-up, it's been a self-run program."

Anecdotal evidence suggests that IRB members are pleased with the mentoring program and that the IRBs benefit from new members' faster assimilation on the board, Lake-Bullock says.

"Our intent is to send out a survey and see how it's doing," she says. "But I've asked people what they thought of the program, and, overall, they thought it was great." ■

Welcome Checklist

- Place a call or write to welcome the new IRB member.
- Inform the new member of date/time of the first IRB meeting and offer to accompany him/her to the meeting.
- Schedule a meeting with the new IRB member in advance of IRB meeting to review process and procedures.
- Introduce the new IRB member to the chair of the IRB committee and assure that he/she becomes familiar with the resources available to the IRB members.
- Introduce the new IRB member to the current IRB committee.
- Assist the new IRB member in applying federal criteria and ethical principles in reviewing protocols submitted to the IRB for review. Devote time to explaining special review circumstances such as research involving pregnant women, prisoners, and children.
- Review the current IRB application forms and discuss how these are reviewed by the IRB.

New booklet educates community IRB members

Veteran community members teach the basics

New members on an IRB always need some amount of education to understand how the review process works and what their role will be on the board.

But community members—who are generally both non-scientists and unaffiliated with the institution—can face an especially steep learning curve, and can feel overwhelmed and intimidated about speaking up at meetings.

At the University of Southern California in Los Angeles, a team is creating a new handbook for IRB community members, designed not only to acquaint them with the basics of IRB review, but also to give them confidence enough to jump in with both feet.

To do so, they've tapped the experiences of sitting community members asking, "What did you need to know when you started?"

Susan L. Rose, PhD, executive director of USC's Office for the Protection of Research Subjects, says she doesn't agree with the attitude that community members should be educated like any other member of the IRB.

"There's an accepted thought that they're the same as the other members and that you're demeaning them if you treat them differently," Rose says. "I think that if you can give your community members the same education as the other members, they shouldn't be your community members.

"If they are not different enough from the routine faculty members or investigators on your IRB, you don't really have community members."

For that type of recruit, who may have little or no experience with the research process, IRB review can be a pretty daunting proposition, Rose says.

"The language is even different. 'Phase 1,' 'Phase 2,' 'Phase 3 clinical trials.' 'Defer.' 'Contingency.' All the words aren't familiar words," she says.

Rose envisioned a booklet that could be made available to new community members, not just to acquaint them with terms and research concepts, but also to give them tips for navigating the waters of IRB review.

Marjorie Speers, PhD, executive director of the Association for the Accreditation of Human Research Protection Programs (AAHRPP), says

that while many institutions provide a lot of training for all their members, most do not provide any specialized program for community IRB members.

"That is something unique, I think, with this project that is taking place at USC," Speers says. "I think this is an innovative project."

A 'foreign environment'

To put the booklet together, Rose tapped **Urvi Patel**, MS, a psychology graduate student at USC who serves as the IRB student mentor, and **Malena Avila**, a stay-at-home mother of three who has served as an IRB community member on the health sciences board for the past five years.

"I've been awed by Malena ever since I came here," Rose says. "She started out quiet and now it's like watching a flower. She will not let certain projects go. She's like a bulldog.

"When we had a little meeting of community members to kick [the booklet project] off, she really was the most interested in doing it."

When Avila started her stint on the board, she says she found the IRB to be a completely foreign environment. "Not only foreign, but I didn't have any allies," she says. "I didn't know who anybody was. I got introduced: 'This is the IRB, IRB this is Malena Avila, she's our new community member.' So everybody knew me, but I didn't know anybody."

Avila says she viewed a video that had been prepared for all new IRB members, but did not get any special education that was targeted toward community members.

Her most important ally in learning the ropes was another community member, who gave Avila her phone number and suggested she call with any questions.

Avila began educating herself at meetings, keeping a notebook of unfamiliar terms, questions that arose during meetings, and anything else that occurred to her.

"Every time I heard something and thought 'Wow! I'm going to be able to use that!' I'd write it down," Avila says. "I wrote down things I thought were interesting, things I thought would be helpful, things where I thought, 'Hey, I don't agree with that.'

"It doesn't mean anything one piece at a time, but over the span of the time I've been there, it's been helpful."

For the community IRB booklet, Avila opened up her own notebook and shared her insights with Rose and Patel.

"Her help was invaluable," Patel says. "We asked her, 'What would you have liked to have known when you started?' and her input really set the roadmap for our table of contents."

The sections in the 50-page booklet include:

- **Expectations for IRB members:** Prospective members can learn what time commitment would be expected of them if they joined the board. Patel notes that many boards meet in the mornings, which could pose a problem for mothers of young children.

"You will be required to commit some time besides the meetings, when you review protocols, at your home or wherever," she says. "We want people to know what they're getting into."

- **IRB procedures:** The book outlines research subjects' basic rights, along with the criteria for approving protocols. Community members are encouraged to ask questions, and given contact numbers for the IRB office if they don't understand some aspects of a protocol.
- **Terminology:** Terms such as confidentiality, privacy, and informed consent are covered. The book describes the jobs of different study personnel: What is a data monitor? What does the principal investigator do?

The book describes the different phases of clinical trials and what occurs in each one. There's also a brief discussion of statistical terms that may come up in the review of protocols.

"We try to briefly cover what these things mean without being too technical," Patel says.

- **Board meeting details:** The booklet describes what will happen from the moment a member walks into the meeting room, including the reading of minutes and the rest of the agenda. This section also explains to members what their options are for voting on individual protocols.

Because the IRB meetings loosely follow Robert's Rules of Order, this section explains those rules, and tells members how to communicate with the board using various motions.

"Then we explain when (a member) might be asked to be a primary reviewer," Patel says. "Most of the time, community IRB members are asked to look at informed consent forms. If we see that they're doing a pretty decent job with the reviewing, they're asked to be primary reviewers—in a sense, it's a promotion."

- **Tips for empowering members:** Patel says that many community members can feel intimidated about walking into a meeting with a group of people who know each other, and who have

degrees and knowledge that they themselves might not have.

"In the beginning, you might feel as if you're not being heard," she says. "That's one we get all the time. So we suggest a couple of things"—including speaking with another member or the IRB chairman after the meeting, or contacting the IRB office for more information or to register a concern.

In her own words

In addition to providing input for the booklet, Avila also is writing a first-person introduction.

"That's the only part that's really in my voice," she says. "The rest is a combination of Urvi's and mine."

Avila says one idea that she felt was important to communicate to other members was the willingness to advocate an opinion in the face of opposition. She says a particular protocol can meet all the listed requirements, and still raise questions in her mind.

"It's more like an ethical or moral issue—should we be doing it this way?" she says. "Could it be retrospective? Do we really need to use these minors for this research? Those kind of issues.

"I think it's one of the reasons IRBs exist, because you have to think about justice as an issue, you have to think about ethics," she says. "Even if you are a lone voter, you need to be able to say, 'I really wasn't quite sold on this particular protocol.'"

In addition to Avila's experience, Rose says a community member on USC's social-behavioral IRB is writing about issues specific to that type of research, and the team has sought ideas and feedback from other community IRB members at the university.

Patel says the booklet eventually will be made available to outside institutions. They also plan to use the information for an on-line module for specialized IRB training of community members, which also would be available to other research institutions.

"The need began with our members, but I've done a couple of searches on-line, and I think this need goes beyond our university," she says. "There are a lot of community members who would like to have a reference like this."

Speers points out that information could be useful to more members than those who are traditionally seen as "community members." She says that many IRB members who may be affiliated with a university—risk managers, lawyers, student members—may lack the same basic background in clinical research.

"The language we use, it's a field that's full of acronyms," Speers says. "If you choose somebody out of the compliance area or out of budgeting, they're not going to know those terms. I think a lot of that really applies across the board."

Patel, who in addition to serving as the IRB student mentor recently joined the board as a member, agrees.

"Working on this project has helped me as I began serving as an IRB member," she says. ■

[Editor's note: The University of Southern California's community IRB booklet should be available on-line in November, and in booklet form in December. To obtain a copy, e-mail Peter Mestaz at oprs@usc.edu.]

IRBs improve recruitment of community members

Boards should be diverse to represent community

Research institutions are becoming more sophisticated in their recruitment and retention of community IRB members, says **Marjorie Speers**, PhD, executive director of the Association for the Accreditation of Human Research Protection Programs (AAHRPP).

The IRBs Speers sees applying for accreditation are doing more than simply trying to find someone unaffiliated with their institutions.

"I think we do a much better job today in selecting community members than we did previously," Speers says. "I think before, it was find anybody sort of outside the university or hospital to sit on the IRB. Whereas now, there are a lot of sharp people who do know about research and understand the importance of it and they are willing to sit on an IRB."

Finding those people takes creativity and a willingness to experiment, says **Susan L. Rose**, PhD, executive director of the Office for the Protection of Research Subjects at the University of Southern California in Los Angeles.

Rose particularly looks for members who have specific experience with a population that is being studied in protocols that go before the IRB.

For example, in a previous position, she learned that researchers with her institution were doing studies involving drug addicts, so she went looking for community IRB members who

could speak to those issues.

"It took me maybe four hours on the telephone but I found a group made up of ex-drug users that worked to make sure that no harm came to [addicts]," Rose says.

At USC, researchers do a large number of gang-related studies, so one of the community IRB members recruited was an activist who mentors high school students involved in gangs.

One good source of community members are subjects from previous studies, she says.

"I try to get some of the researchers who are sensitive to keep their eyes peeled for some of their subjects who might be interested," Rose says.

Speers says it's important to have a critical mass of community members on an individual board to give members the moral support they need to voice their opinions. At USC, for example, Rose says that there are 3-4 community members on each of the various boards.

"I actually think that this is an area where we've seen real change," Speers says. "Institutions will have more than one community member or unaffiliated member on the IRB. They may have several. They'll have individuals who represent different perspectives, particularly different ethnic groups, if the IRB is reviewing research that is conducted among different ethnic groups."

Another practice that can help new community members feel empowered is to assign them mentors, says **Urvi Patel**, MS, a psychology graduate student who serves as an IRB student mentor at USC.

"We really push this idea of veteran community IRB members mentoring newbies," Patel says. "Even just having a phone number to call at that point, when you're new and everything's overwhelming, goes a long way."

Speer says the culture of IRBs has been changing over the past few years, as new chairmen come on board, encouraging a more participatory style during board meetings.

"They're involving others, and making sure everybody has a voice in the discussion," she says.

Speer notes that federal regulations do not require a community member or non-affiliated member to be present to have a quorum for an IRB meeting—they require only that a non-scientist be present.

"But in our standards, we really want the person with the local perspective to be there," she says. "So I think that the accredited organizations are very concerned about the diversity of opinion and involving the community in the decision-making process."

Speers says that one area all IRBs should be vigilant about is trying to recruit an ever-more diverse group of community members. She notes that in some major metropolitan areas, there may be 100 languages being spoken.

"Not that you'd want all 100 languages represented, but you can probably never have too many community members when you're in such a diverse community," she says. "We're always striving with the IRBs to make them more diverse, more inclusive of the communities where they're conducting the research." ■

IRB's electronic system is office's 'saving grace'

System saves volumes of paper, time

When the IRB at the University of Utah in Salt Lake City, UT, spent two years seeking accreditation, the institution's electronic system was what helped most, the IRB director says.

"Our saving grace is the electronic system," says **John Stillman**, director of the institutional review board. The IRB received full accreditation in June, 2007, from the Association for the Accreditation of Human Research Protection Programs in Washington, DC.

Before switching to an electronic documentation system, the IRB review process was cumbersome and a paper burden to investigators and IRB members, Stillman says.

Investigators would have to give the IRB about two dozen color-coded copies of each protocol submission, Stillman says. "We didn't have the budget to make copies," he notes.

The workflow under the electronic system is faster and more efficient, Stillman says.

The electronic system has made it possible for the IRB office to keep staffing level even as the workflow has increased, and it's cut other costs, Stillman says.

"We used to buy 1,000 boxes of paper a year, and now we buy 50 boxes," Stillman says. "But where the savings really comes from is all across the campus, investigators can log-in and no longer have to submit paper protocols."

Investigators report that the protocol submission process is very easy and fast now, and if the investigator has all of the necessary information available, he or she could complete the electronic

form within an hour to 90 minutes, Stillman says.

Here's how the institution implemented and uses its electronic system:

• **Select and modify software:** The institution chose Click Commerce® software, which initially was purchased from Web Bridge in Beaverton, OR, Stillman says.

"We were early adopters of the product," he says. "We got our version of software, and it required a great deal of modification in house."

A team of three information technology professionals helped make the necessary modifications after the software was installed, Stillman says.

"In the university there's a health science center, including a university hospital, school of medicine, and associated groups, so we had a nice information technology infrastructure that already existed," Stillman says. "They help us manage our hardware."

Also, the institution bought three servers to run the system, relying on National Institutes of Health-funded grants totaling $500,000, he says.

• **Decide how to handle work flow issues:** "We hammered out the workflow by identifying how we do it on paper and deciding which issues we needed to identify," Stillman says.

The first piece was to build work flows into the system, and these were dictated primarily by the IRB staff, he notes.

Stillman, the IRB staff, IRB members, key research professionals, and a computer programmer all attended meetings on the subject.

"We did a lot of user testing to see what they wanted to see and what would be most efficient," Stillman says. "There probably were 10 people at the meetings, and they were held multiple times a week at first and then once a week."

The meetings continued for about 18 months. Slowly the meetings were reduced, and now the process is dictated by the site manager and program manager, he adds.

• **Integrate other programs:** The goal always was to integrate the electronic system as much as possible.

"We've evolved to a system where we've just integrated the conflict of interest [committee] online," Stillman says. "So you can put in the information once, and it populates various systems."

The conflicts of interest committee can review the protocol submission and provide feedback to the IRB—all electronically.

The next step would be to integrate clinical communication, he says.

For example, if an investigator is doing research with cancer patients at the university, then the institution's clinical cancer investigation committee (CCIC) also would need to give approval, Stillman explains.

Once the CCIC is integrated into the electronic system, the submission process would be seamless for both the IRB and CCIC. The same integration could be done with all committees reviewing research protocols, he says.

The IRB asks the various committees if they want to be integrated, and the hope is that they all will as soon as it's possible, Stillman says.

"If they say they'd love to be a part of it, we develop it and test it with that group and then move on to the next group," Stillman says.

• **Train staff, IRB members, and investigators to use electronic system:** The institution provided departmental training and hired a fulltime trainer who worked with each individual, Stillman says.

However, since everyone in the IRB office had been involved with the electronic system since it first was implemented, there was not as much need for training once it was completed, he notes.

IRB members and investigators also were involved in building the software process and could submit comments about how to make it more user-friendly.

"It'd take their comments to the developer and sometimes implement the enhancements within a couple of weeks," Stillman says.

"It's an intuitive system," Stillman says. "So a researcher, who has never used it, can fill out the form electronically once he gets a log-in and password."

In fact, the electronic process is so easy that the IRB office gets more questions about regulatory issues than it does about how to use the electronic submission system, Stillman says.

• **Market electronic system institution-wide:** "The key selling point was the idea that investigators didn't have to submit paper and copies and that they had their own web-based workspace to access all of their own projects," Stillman says.

Also, investigators could see where they were in the queue.

Besides saving paper, the electronic process is much more flexible for investigators. "Now if an investigator's study has an expedited review, it can be logged in and done very quickly," Stillman says. "Before, the investigator might receive a packet with questions, but now it's a nice application that's pre-vetted by the IRB staff,

and it allows users to log in anytime day or night."

These features helped to sell the system to investigators. "We were surprised in how well it was received," he says. "We got a lot of support from day one."

IRB members also needed to buy-in to the process. The electronic forms clearly show questions related to the type of protocol that has been submitted, Stillman says. If the electronic process had been difficult to maneuver, the IRB would have protested, he says.

"Most found it easier to work with the protocols on-line," Stillman says. "Older IRB members might not have liked it and asked for paper, but now they're used to it."

In the future, the electronic system will permit the IRB office to run reports showing how long a study was in the pre-review process and how long the IRB considered it. All of this information could be useful for quality improvement projects, Stillman says. ■

Research institute has scientific review prior to IRB review

IRB's time is free for safety, ethics

At least one research institute has found a solution to the problem of finding time for IRB members to review protocols for both the science and ethical issues.

The answer is having two separate committees, each charged with a more precise role.

"In my opinion, it's all advantageous," says **Brenda A. Higgins**, CIP, manager of regulatory affairs for the OhioHealth Research Institute, which is part of OhioHealth in Columbus, OH.

"It takes the scientific review off the shoulders of the IRB," Higgins says. "Then the IRB can focus on safety and being a patient advocate."

All members of the research committee and the IRB are unpaid volunteers.

There are 15 IRB members, including a chair who has been with the committee for about eight years, Higgins says.

Many members of the IRB have been serving on the committee for more than five years, including a retired medical sociologist who has served since 1990, she adds.

"So we have longevity on the IRB, and they seem to enjoy each other, which is nice," Higgins says.

The process is especially effective for investigator-initiated protocols that are done by medical residents, pharmacists, and nurses, Higgins notes.

Since OhioHealth has a teaching hospital, surgery residents, obstetrics/gynecology residents, and orthopedic residents are required to do a research project before they graduate, she adds.

Also there is a magnet program for nurses, so there are many nursing studies generated, as well.

"The research committee members can spend a lot of time looking at these protocols, and they can guide [the new investigators] and give them good advice," Higgins says.

Here's how OhioHealth Research Institute's two committees work:

• **Logistics:** The research committee, which reviews protocols for scientific validity and will see the protocols first, meets on the first Wednesday of each month, and the IRB meets on the third Thursday of each month.

The two committees are composed of separate members, except for the IRB chair who also serves on the research committees, Higgins says.

"So he has familiarity with the studies by the time they get to the IRB," Higgins says.

Some studies given a scientific review are not submitted to the IRB, and these include expedited chart reviews, process improvement work, and retrospective reviews that the IRB chair can sign off on, Higgins says.

The scientific committee includes members who have expertise in various disciplines, including cardiology, oncology, epidemiology/statistics, infectious diseases, gynecology, hematology, pharmacy, etc. There are a dozen members and no alternates, she says.

The research committee's meetings typically last one hour, and the IRB's meetings last 3-4 hours. The research committee meets at 7 am, and the IRB meets at 4 pm—times that have proven most convenient for committee members, Higgins says.

The research committee gets a copy of the complete protocol, as does the IRB's selected reviewer/presenter for that particular protocol. Other IRB members receive a modified protocol with the application, abstract, and informed consent form, Higgins says.

"All IRB members have some part of the protocol, but only the reviewer and IRB chair have the complete protocol," she adds.

If a study involves a controversial or new device, then the IRB will ask the principal investigator to come to the meeting and explain it, but this usually is not necessary, Higgins says.

Six or seven days after the IRB reviews a protocol, a letter is sent to the investigator, Higgins says. The IRB also reviews all amendments and all adverse events.

The person who originally reviewed a protocol is assigned any information about serious adverse events that are reported, Higgins says.

"So there is a continuum there, and the reviewer looks at the SAE to determine whether it was study-related, and then sends the information back to me, and I report those findings to the full IRB," Higgins says. "I do the same thing for amendments that signal a change in the protocol."

• **What the scientific committee looks for:** "Each protocol that goes to the research committee has to have two reviewers, and both have to do a written review," Higgins says.

The two written reviews are sent to the IRB reviewer and chair, along with minutes from the research committee meeting, she says.

The scientific committee answers the question of whether the study's science is sound, and the IRB looks at the study's safety, efficacy, and patient advocacy, Higgins adds.

"One example is a nurse who is doing a study about foreign-educated nursing because of the growing nursing shortage," Higgins says.

"We're bringing in nurses from other countries, and her study is how to get their impression of how helpful American nurses are to them," Higgins explains. "She has 10-12 questions for them, and her study will be an interesting piece because of the growing need for nurses."

The scientific review committee would ask her these types of questions:

• Is her sample size large enough to bring the results she's looking for?

• Is her questionnaire well done?

The scientific committee reviewed her questions for the nurses and questioned the way one question was worded, Higgins recalls.

The question was this: "Describe a negative experience that applies to nursing practice and which stands out as memorable."

The committee suggested the investigator also ask the subjects to describe a positive experience to obtain more information, Higgins says.

Once the investigator had incorporated the scientific committee's suggestions into her protocol design, she submitted it to the IRB because she planned to publish the study or present it at a conference, Higgins says.

"If you're going to represent the institution in any way, then it needs to go to the IRB for their approval," Higgins says. ■

HIPAA can be a barrier to research participation

Effect most prevalent among African Americans

The implementation of the Health Insurance Portability and Accountability Act (HIPAA) has added length and complexity to the process of getting research approved.

Now there is some evidence that it may actually affect recruitment of subjects, who are turned off by the legalistic language and whose suspicion is aroused when asked to sign an authorization form.

A study conducted at Emory University in Atlanta looked at African-American patients, finding decreased willingness to participate in a hypothetical study after reviewing both informed consent and HIPAA forms, compared with patients confronted only with an informed consent document.

Anne Lang Dunlop, MD, MPH, an assistant professor of family and preventive medicine at Emory, says she believes the impact of HIPAA isn't limited to African-American subjects.

"I think the concerns about HIPAA may be more prevalent among African Americans," Dunlop says. "But this is probably an issue that affects other racial and ethnic groups as well."

She says the results point to the need for further study of the potential impact of HIPAA on the willingness of African-American individuals—as well as individuals of other racial and ethnic groups—to enroll in clinical research studies. The study also suggests a need to develop strategies that protect patient privacy that don't overwhelm participants with difficult forms.

"We need to make sure that we're looking at our informed consent and HIPAA authorization forms through the patient's lens," Dunlop says. "I think sometimes we take what we know as researchers for granted. But we don't consider that a lot of people, even those with a college education who might not have a science background, aren't necessarily understanding it."

Suspicious of forms

Dunlop says she began to focus on HIPAA after an experience she had recruiting subjects for a study. Her team was trying to sign up mothers of very low-birthweight babies for specialized medical care at no cost to them, and initially, found the women to be excited about enrolling.

"Then I would haul out that informed consent and [separate] HIPAA form," she says. "And many of the women who were initially quite interested said, 'Wait a minute—what are you asking me to sign?' It raised a lot of suspicion and concern about what we were really doing. What were we tracking? Why were we asking them to sign off on these forms?"

Dunlop says her perception was that it was the HIPAA form that was causing the most concern, and attributes part of the problem to the fact that some mothers she was recruiting may have had drug problems or other issues that caused them to worry about keeping custody of their children.

"In going through the HIPAA form, they would see that we were sharing information with public health authorities—the government, basically," she says. "They couldn't understand why the information was being shared. And I don't think the form necessarily laid that out in a way that was easy to digest."

Dunlop began to wonder whether concerns about HIPAA forms were dissuading other potential subjects from participating in research.

It's a difficult question to study, because obtaining HIPAA authorization is mandated by federal law. So Dunlop created a hypothetical study, asking patients at Grady Memorial Hospital, Atlanta's large public hospital, and at Emory's own outpatient clinics to review the forms and give their impressions. What did specific sections of the informed consent and HIPAA forms mean to patients? Did any of the sections raise specific thoughts or concerns? Did they affect patients' willingness to participate in this hypothetical study?

Dunlop says her study focused on African-American patients because of the well-documented mistrust that population has had about medical research in the wake of the infamous Tuskegee Syphilis Study. She says it also is clearly demonstrated that African Americans are underrepresented in clinical research studies.

"Among people of all races and ethnicities, you will have people who have mistrust of research, medicine, and physicians," Dunlop says. "But I think because of historical wrongdoings, this is just more prevalent among African Americans.

"I wanted to hear from African-American patients in the South, close to Tuskegee, about why they would or would not participate in a research study and look at what kinds of concerns are potentially raised by the informed consent and HIPAA processes."

Study tests separate form

The hypothetical Phase 3 study compared an experimental antihypertensive drug with an established medication. The consent form and HIPAA documents were prepared according to the Emory IRB's existing guidelines. Dunlop says she used a separate form for HIPAA because Emory, and many other institutions, require or suggest this approach, particularly with low-literacy populations.

Potential subjects were asked by Dunlop's research team to participate in a study of why people do or do not take part in medical research. Those who agreed were asked for demographic information, but did not have to reveal identifying information.

One group reviewed only the informed consent document for the Phase 3 study with the study team. They then were asked whether they would be willing to participate in the study, and to give a reason for their decision.

A second group reviewed both the informed consent form and the HIPAA form. Those participants were asked not only whether they would enroll in the study, but also whether they would release their information for participation in the study.

Responses were audio-recorded and analyzed. Overall, those who received both the HIPAA form and the informed consent document were less willing to participate in the Phase 3 study—only 31% would agree, compared to 42% of those receiving only the informed consent form. Intergroup differences were particularly marked for males, those age 40 or older, and those with high school or less education.

Those receiving the HIPAA form who did not want to participate in the Phase 3 study most often cited some form of mistrust of research, researchers, or research institutions as their reason (about 53%, compared to 40% of those seeing only the informed consent document).

Additionally, nearly 40% of the HIPAA group cited privacy concerns, compared to less than 3% of the non-HIPAA group.

"When we compared the people who were shown HIPAA to those who just got the informed consent, privacy concerns were higher in every group that saw the HIPAA form," Dunlop says. "That was a result I didn't expect going into this."

Also surprising to Dunlop was the number of people in the HIPAA group who expressed concerns about how participating in the study would affect their health insurance eligibility or coverage. It was a response that she and her research assistants hadn't anticipated at all.

But in retrospect, it made sense. After all, Dunlop notes, the proper name of HIPAA is the "Health Insurance Portability and Accountability Act," which is clearly spelled out in the form.

"I think many of us—doctors and researchers—we might just read right over that because it doesn't mean anything to us. It's just HIPAA," she says. "But people who are not so overly exposed to this acronym saw that and said, 'Health insurance? What does this have to do with my health insurance?' And it really raised concerns."

She says the health insurance concerns were raised by younger and older participants. Those who had a high school education or more were more concerned than less educated participants.

"The people who were more carefully reading it were the ones who seemed to have the most concerns about it," Dunlop says.

Easing mistrust

Dunlop is quick to point out that concerns over the HIPAA form were not the principal reason that participants gave for declining to be in the study. Overall, fear of side effects was the most common reason cited; structural barriers and lack of perceived benefit were also common reasons.

Building on her current work, Dunlop's team is in the process of testing whether showing participants an educational video that explains how subjects are protected in research can help combat mistrust as a reason for non-participation.

"I think that sort of education of patients, potential participants, or even just laypeople, to help them realize what research is and that there are protections in place, would probably do more to foster trust in research, research physicians, and research institutions than anything else," Dunlop says.

She says that she does not believe IRBs are at fault for making the HIPAA requirements too daunting, since it is a federal mandate that institutions are concerned about fulfilling.

"I think for a lot of these institutions, their livelihood really depends on the blessing of the federal government—knowing they're doing everything according to the standards," Dunlop says. "They tend to take a very conservative approach."

But she thinks that institutions should consider showing more flexibility with HIPAA, taking care that their approaches pass muster with the U.S. Department of Health and Human Services.

"We really need to be doing more research to find an alternative means of [carrying out] informed consent and HIPAA that's simpler and

CE/CME Objectives

The CE/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 medical education program by reading the issue, using the provided references for further research, and studying the questions at the end of the issue.

Participants should select what they believe to be the correct answers, then refer to the list of correct answers to test their knowledge. To clarify confusion surrounding any questions answered incorrectly, please consult the source material.

After completing this activity at the end of each semester, you must complete the evaluation form provided and return it in the reply envelope provided to receive a letter of credit. When your evaluation is received, a letter of credit will be mailed to you.

COMING IN FUTURE MONTHS

- Improve standard operating procedures
- Recruit cultural consultants for international studies
- Create stellar quality improvement form
- Using decision aids in clinical trials

still satisfies the law," Dunlop says.

Dunlop adds that a recent comparative analysis of the HIPAA Privacy Rule and the Common Rule revealed that requirements for individual authorization overlap substantially, suggesting that a minimal addition of text to the informed consent form might satisfy authorization requirements under the HIPAA Privacy Rule.

CE/CME *questions*

13. Which of the following actions are appropriate for a checklist tool for an IRB mentoring program?
    A. Place a call or write to welcome the new IRB member.
    B. Inform the new member of date/time of the first IRB meeting and invite to accompany him/her to the meeting.
    C. Introduce the new IRB member to the chair of the IRB committee and assure that he/she becomes familiar with the resources available to the IRB members.
    D. All of the above

14. It's important to recruit a number of community members for an IRB, so that they will feel more empowered to speak up at meetings.
    A. True
    B. False

15. What is an advantage to having a committee that's separate from the IRB review research protocols' science?
    A. This frees the IRB to spend time on just the safety and ethical issues
    B. This reduces the amount of time necessary for each protocol review
    C. It's easier to find members for the science committee
    D. All of the above

16. What percentage of potential study participants who viewed a standard HIPAA form cited privacy concerns as a reason for not wanting to enroll?
    A. 3%
    B. 40%
    C. 75%
    D. 83%

Answers: 13. (d); 14. (a); 15. (a); 16. (b)

If the federal government agreed with that assessment, this could ease the potential negative impact of HIPAA on research enrollment, as well as its potential for raising concerns about privacy and health insurance eligibility and coverage, Dunlop says. ■

Reference

Dunlop AL, Graham T, Leroy Z, et al. The impact of HIPAA authorization on willingness to participate in clinical research. *Ann Epidemiol* 2007 Aug 4; Epub ahead of print.