

New booklet educates community IRB members

Veteran community members teach the basics

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 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 opr@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