

"For NIH-funded studies we have a more complete approach," she says. "In other studies, we consider the issues and see what investigators propose."

IRB members also need to keep in mind that investigators want to give information back to participants, and they're often convinced their work will solve medical problems.

"But that's rarely the case for a single disease or research project," Hohmann says. "It takes many studies to produce the test that says, 'We can do this and we know what it means.'"

Researchers cannot take a short cut to scientific certainty just because they might have found a genome that is associated with sudden death according to a single study, she notes.

"These are complex [ethical] areas, and they depend on the state of science in a given field," Hohmann says. ■

Reference

1. Managing incidental findings in human subjects research from imaging to genomics. University of Minnesota, Minneapolis; May 2007.

Student mentor serves on IRB, helps other students navigate system

Program improves IRB efficiency

Fledgling student investigators at universities can find human subjects protection regulations complicated and overwhelming and the IRB bureaucracy intimidating and scary.

The University of Southern California in Los Angeles has created a unique resource to help them: a specially trained graduate student who both serves on the IRB and meets with students to help them navigate the IRB system.

Urvi Patel, MS, who currently serves as the IRB student mentor at USC, says that while the school has a good web site that explains to students how they should prepare and submit an IRB application, many students still are intimidated by the process.

"They don't know where to start and they're just looking for direction," she says. "And that's where I come in. Knowing there's a student there just to help them makes it less intimidating for them, I think.

"Once you tell them you should do this first,

and you should do this next, you can visibly see the load being lifted."

The position was the brainchild of Susan L. Rose, PhD, executive director of USC's Office for the Protection of Research Subjects (OPRS). Rose asked for the position soon after coming to the university.

"When I came here, no students were on any of the IRBs," Rose says. "The woman who runs the school sort of thought of my new office as an experiment where the budget should be fluid. So I said to her, 'I only want two things — I want a student and I want a web site.' And she did both."

The student mentor position is a 20-hour-a-week graduate assistantship assigned to the OPRS. In addition to serving on one of the IRBs, the mentor is expected to help with educational programs for new student investigators and to help out with OPRS projects such as a recent community IRB booklet.

Rose says she's lucky to have such a well-funded assistantship in her office.

"There's quite an expense connected with the student mentor," she says. "It still shocks me after four years of it. The student gets tuition, and gets all benefits paid. They work half time if they can and they get a stipend that is pretty hefty. So it's not cheap."

But she and Patel point out that the institution benefits as well — from having a necessary student voice in IRB deliberations and from student IRB applications that are more complete and require fewer changes.

"It makes for a more efficient IRB," Patel says. "Ideally, I'm that first filter that makes their jobs easier as well."

Finding the right candidate

Rose says it's been a challenge finding the right people to serve as student mentors — Patel is the third to hold the job since it was created four years ago. They need to be technology savvy, because the IRB process is on-line. They must have excellent interpersonal skills, dealing not only with younger students but with non-traditional older students and even with professors who may ask for their assistance with protocols.

Because of the necessary time spent training them in human subjects protection, Rose says she looks for someone who isn't in his or her last year of graduate school. "You don't want to go to all that work and then they're gone," she says.

She says that in the past, she's tried to ask the

schools that account for most of the IRB applications to recommend possible candidates, but they rarely respond.

Patel, a psychology graduate student, says she was contacted by an IRB reviewer who thought she might be right for the job — ironically, because she had contacted the office so often asking questions about her own research projects.

“Whenever I was filling out my applications I had a bunch of questions, so I would call them all the time and they got to know my name,” she says. “We’d have conversations about how it would be a good idea for schools to have a graduate student who helps other students or professors, to filter out some of that before it gets to the IRB application.”

Patel also had served previously on an IRB at another institution.

Once selected for the job, Patel spent several months with her predecessor, learning the ropes. She not only had to know the regulations, but also the process of working with USC’s IRB. Rose took Patel to IRB meetings on the USC campus, as well as at other area research institutions.

Patel’s work was shadowed by IRB staff until they were comfortable with her expertise.

Teaching groups, advising individuals

In her role at USC, Patel spends a lot of time with Rose presenting educational programs for groups of students.

“We have two different talks we give,” Patel says. “One is very general, covering the basic principles. Why does the university need a human subjects program?”

“Then we have a more specific talk, which is given to students who’ve passed a certain point in their graduate career so they have the methods of their research down, and they’re ready to start submitting on-line. The second group understands why the IRB is needed; they just need to figure out how to submit an application.”

Rose says they’ve recently expanded their reach, doing sessions for second-year medical students who are planning research projects.

In addition to the larger educational sessions, Patel also meets one-on-one with students who seek her out, or who are referred to her by the IRB because of difficulties with their applications.

Among the most common problems she sees are researchers who are unsure what level of review their projects fall under.

For most students the one thing that provides the most source of concern is the appropriate

level of review,” she says. “They don’t want to submit an application that is a level above or below that.”

In addition, students often don’t know that the IRB provides all the necessary templates on-line. They will submit a self-composed informed consent form or other document, which the IRB rejects because it doesn’t meet their requirements.

And then there are the students whose work is even less IRB-ready.

“The student will submit the application and a staff reviewer will send it back and say, ‘You need to see the student mentor,’ because they didn’t have a complete application. There’s not even enough information for them to review it,” Patel says.

No ‘dumbing down’

Patel says she makes two important points in dealing with students:

- **Her goal is not to have a student “dumb down” a study**, removing any potential barriers simply to assure easy passage through the IRB. For example, she won’t counsel a student to jettison a controversial survey simply to avoid a tougher review.

“We need to maintain the integrity of the research,” she says. “That’s the most important thing, not how to get it through the IRB faster. Because when they leave, they need to be proud of the research. I say, ‘Your research has your name on it, you want it to be something that you’re proud of.’”

- **She’s there to help a student identify and address ethical issues**, not as a consultant on experimental design.

“I’m not their adviser,” she says. “They have to work through all the methodology before they see me.”

Rose says that can be a problem, when faculty advisors don’t prepare students well enough.

“You have mentors who do not mentor and throw their students to the wolves,” she says. “Students sometimes come to our IRB mentors with design issues and basic project issues.”

Rose says that all of the women who have served as IRB student mentors have brought personal qualities and interests that added value to the position. For example, Patel, a teaching assistant fellow, is seeking to provide more information to other TAs who are encountering student projects in class.

Rose says Patel is extremely good at connecting with students, even those who may be many

years older than she is.

"Urvi has been helping a lot of people who are returning or older students who don't know how to deal with the [information technology] side.

She's helped them with things that they can't do, and the students are comfortable with her.

"I just can't say enough good things about her."

Patel says her work with the IRB has affected her own research.

"I'm way more thorough in my explanation of everything I do," she says. "Why did I decide to do this? Could I have done without it?"

She says she hopes to eventually land a faculty position at a major university, and believes her IRB experience could help her in that goal.

"I think it's very marketable for me to have gone through the whole IRB process at two different universities," Patel says. "I think it's a selling point for me to say I can wear the professor's hat and the researcher's hat but also be someone who's involved in the IRB as well."

Rose says she believes universities have an obligation to involve students in the IRB process, and has tried to convince various departments at USC that they should have their own graduate students to help students in the earliest stages of applying to the IRB, but with no success.

She thinks schools could create mentoring positions similar to USC's without necessarily incurring the same expense.

"I can't rave enough about it," Rose says of the mentoring program. "I cannot imagine my job here without it." ■

Psychological association seeks to ease problems between IRBs, researchers

Communication is a two-way street

A special task force of the American Psychological Association studying the tensions between IRBs and psychology researchers has released a list of recommendations on how to address those tensions.

IRB members bracing for an angry denunciation of their work may find themselves pleasantly surprised.

While the committee does note complaints about IRBs overreaching and misunderstanding the nature of behavioral research, it also asserts

that psychological researchers should do a better job of understanding IRBs and calls for collaboration to achieve the common goal of improving protection of research subjects.

"IRBs and psychologists who are doing research both have exactly the same goals in mind," says **Thomas Eissenberg**, PhD, associate professor of psychology at Virginia Commonwealth University in Richmond, VA, who served as the chairman of the APA Presidential Task Force on Institutional Review Boards and Psychological Science.

"They want to protect participants and they want to see the highest quality of research completed at their institution. That means they're on the same side. What we ought to be doing is working together to make sure that we protect participants as effectively as we can while maintaining the highest quality of science as we can. And we can do that if we work together in a collegial way."

The task force made five major recommendations to the association (see **accompanying article on p. 7**), focusing on helping each side understand the other better and working together to provide evidence-based IRB policies on how to best protect participants in psychological research.

"I think a lot more research has to be done about what the problem is and what the potential solutions are and whether those potential solutions are likely in fact to improve the problem," Eissenberg says.

Presidential interest

Eissenberg says he was drawn to the IRB project by his work on the APA's Committee to Advance Research (CAR), which handles a range of issues involving responsible and ethical conduct of research.

He says the association's 2007 president, Sharon Stephens Brehm, PhD, named IRB issues as one focus of her presidency, and discussed the matter with the CAR.

"She identified this tension as being important amongst her constituency, and she decided to appoint a presidential task force on IRBs and psychological science," Eissenberg says. "Because I was involved with the CAR discussions so much, I got nominated to chair the committee."

Eissenberg came at the issue not only as a psychological researcher but as a member of VCU's IRB. He says his experience with the board has generally been a good one but like