

We're also going to look at, on the subpart A subcommittee, IRB membership requirements. You've often heard that other committees have looked at this and there are people who suggested various percentages of non-affiliated members, we'll we're going to take a look at that and make some recommendations of what IRB membership should look like.

Another activity is that we have had a panel for some time on IRB review models. This panel discussed various models of IRB review, such as the traditional institutional review board, which is located at the institution that does the research, to the independent IRBs, otherwise known as the commercial IRBs. And there are maybe between 35 and 40 now. We've looked at central IRBs and community-based IRBs.

There will be a conference held Nov. 20-21 in Washington, DC, where we're going to continue our examination of IRB review models to try to provide guidance to institutions contemplating developing a relationship with an independent IRB. How should that partnership look like? How should the responsibilities be divided up? What about liability issues and that entire sort of thing.

IRB Advisor: So you are going to come up with a model that IRBs can follow?

Prentice: That's the idea.

IRB Advisor: And that would include a change in recommendations on the breakdown of the members' expertise and things like that?

Prentice: Probably. The agenda's not set. What we want to do is have all of the stakeholders involved in this. We want representation from the independent IRB world, the academic IRB world, the central IRB world. We want to have general counsels from various institutions, who are worried about liability. We want them to be at the table, so all of the stakeholders can be at the table so we can discuss all of the issues. Get them all out at the table and figure out what kind of a system should a given institution adopt in consideration of one, obviously the need to protect the rights and welfare of human subjects, but also the fact that it's important that we foster research for the benefit of human society. Also, if you look at a typical multi-center clinical trial, which may involve 100 sites, to go through 100 IRBs just is not cost effective. So we've got to get a better handle on what is the best mechanism to review multi-center clinical trials, where you have an academic institution participating as one of the sites. Or where you have 50 academic institutions participating as sites, and you've got another 50 who are community hospi-

tals that may not have an IRB, or individual doctor's offices or clinics who don't have IRBs. Is it really cost effective to have 50-60 IRBs reviewing one single clinical trial where you can't change the design of the trial; the only thing you can do is revise the consent form. These are some of the issues that we want to examine. ■

Ethnography proposals pose problems for IRBs

Lack of details or written forms can cause conflict between researchers and IRBs

When an IRB considers a proposed study, the devil is in the details: Exactly what are you studying? Exactly how? Who will participate? When? For how long?

Ethnographic studies look at groups of people in their own communities, often in foreign countries and among cultures that may not be literate. Studies tend to be open-ended and change over time, as the researcher learns more about the community.

Combining those two elements — detail-driven IRB requirements and fluid ethnography studies — often can lead to conflict, says **Rena Lederman**, PhD, associate professor of anthropology at Princeton University, Princeton, NJ. Lederman, who is herself an ethnographer, is also a member of Princeton's institutional review panel.

Lederman says the conflict between ethnographers and IRBs comes because of a fundamental disconnect between the IRB's assumptions about research and the way in which ethnographic research is conducted.

"There's a huge mismatch between ethnographic fieldwork and what the Common Rule assumes about research," she says.

"Consequently, the main IRB guidebooks, the basic IRB handbook, the NIH training course, have assumptions about what research is that are not coordinate with the conventions of ethnography."

She says ethnographic proposals look "incomplete" to IRBs, lacking details in such areas as when research will start and end, exactly who will participate and what questions will be asked.

"Ethnographic research is maximally undemarcated — you can't really say when research begins and ends in ethnography," Lederman says. "Very frequently, especially in ethnographic sociology, researchers get research

ideas from life experience, even before they become sociologists. So you can't really say when the research started."

Because ethnographers in sociology and in sociocultural anthropology go to where their informants are, and allow those informants to shape the topics that will be studied, the ethnographer is not in control of the study in the way that a researcher in a lab would be, she says.

"Not only are you embedding yourself in the home turf of the folks in whom you're interested, you're in effect 'apprenticing' yourself to your informants," Lederman says. "They're in charge. They have a shaping influence on the research process."

This creates problems with the standard IRB application, which demands all the details that ethnographers can't give, says **Donald K. Robotham**, PhD, a professor of anthropology and IRB member at the City University of New York in New York City.

"The changes requested [by the IRB] often ask proposals to be more specific in explaining how informants will be chosen, how many, length of 'interview,' a more detailed interview schedule and so forth," Robotham says. "The chief difficulty here is that the IRB treats ethnography as qualitative sociology or psychology."

Using 'mock-ups'

Lederman says some ethnographers may try to fulfill the IRB's requirements by producing a "mock-up" of the questions they'll ask and the informed consent they'll obtain from participants.

"People come up with sample questions," she says. "The problem is that that feels fake. You're in effect being forced to make something up, something that will almost surely be jettisoned in deference to your informants' interests and emphases, once you're in the field."

"When ethnographers are forced to provide a mock-up of the conversations they might have with their interlocutors, I wouldn't say it's lying, but it is artificial, and it doesn't help IRBs really understand what ethnographers actually do. It contributes to misinformation about ethnographic fieldwork."

Robotham believes that conflicting assessments of risk lie at the heart of much of the IRB/ethnographer conflict. The problem drives IRBs to require the most specifics possible from ethnographers at the outset of a study.

"Many [IRB members] feel that without those specifics, they in fact cannot discharge their responsibility under the law and under IRB regu-

lations and procedures to protect research subjects from undue risk," he says.

In fact, Robotham believes the most recent IRB training protocols geared toward qualitative methods and ethnography actually heighten this conflict rather than resolving it.

"My sense is that in the past, the IRB drew a sharp line between reviewing the proposal for human subject problems as distinct from methodological problems and stayed away from the latter," he says. "The tendency now is to feel that the obligation around risk protection empowers the IRB to scrutinize methods more carefully and to call for a review of particular research methods which they may find wanting."

From her discussions with ethnographers across the country, Lederman says she believes the problems with IRBs are "pervasive, and getting worse and worse."

But she says appropriate, enlightened IRB review of ethnography is possible.

Lederman served on Princeton's institutional review panel for four years in the 1980s and again for the past two years.

She says she's seen a real difference in the way ethnography proposals are handled during her two stints on the panel, which only handles social science research, because Princeton doesn't have a medical school.

"It's always been necessary to educate other members on IRBs about ethnography, because ethnography is anomalous," she says. "It's generally an unfamiliar research strategy to the usual folks who end up on IRBs — social psychologists and survey researchers, and obviously, biomedical people (at institutions with medical schools)."

"In the '80s, at Princeton anyway, the other members weren't particularly aware that ethnography is all that different from other kinds of social science research," Lederman says. She says that after continually explaining ethnography proposals to the other members, she was asked to write a memo outlining the basics about the research strategy. But she remembers that it didn't seem to help.

"My sense was that it didn't have a lasting impact," she says. "Despite my memo, there wasn't any perceptible institutional memory on that issue. The problem needed to be addressed, more or less every time, freshly."

However, in her most recent term on the panel, she thinks there's a better understanding that ethnography is different, and needs to be handled differently by an IRB.

"The board members and particularly the secretary that we've had for the past eight years, are aware that they need education on ethnography, so that certainly helps," she says. "Their strategy was that you want to bring people into the process who have competence in all the varieties of social science research."

She says Princeton's IRB sees a small number of ethnographic proposals, most from the anthropology and sociology departments. Because of the IRB's manageable workload, its reviews are accomplished fairly quickly, within about two weeks.

"Our IRB process is very respectful," she says. "We appreciate one another. I always come away from IRB meetings with a sense that the members of the panel are generous with their time and thoughtful and smart in the reading of individual proposals."

Robotham joined CUNY's IRB in 2004, by which time it already had been reviewing ethnographic proposals for several years. He, too, says he finds his board to be flexible in its approach to ethnographic studies.

"This is largely because they already had considerable experience reviewing projects from psychology and to a lesser extent from education, which used qualitative methods," he says.

Boilerplate, subcommittees could help

Lederman is actively working to help smooth the path for ethnographic proposals at Princeton.

She is working with sociocultural anthropologists in her department to produce a kind of boilerplate language that can be put into their proposals. This language would work toward standardizing the ways in which the ethnographic process is described, so that ethnographic proposals will be easier for IRB members to understand and evaluate.

"I'm trying to develop language — which is challenging for ethnography, given its unfamiliarity — that will become familiar enough to the board members that they won't have to rethink the key issues every time."

She compares it to the language commonly reviewed by her IRB when it considers psychology research that involves the use of functional magnetic resonance imaging, or fMRI, to view the active brain.

"Researchers using fMRI at Princeton have an elaborate set of boilerplate responses for the basic [IRB] full review form," Lederman says. "It describes the safety procedures and the standard operating procedures for that kind of research. Whenever our IRB gets an fMRI proposal to review, there are sections that we have already approved from previous proposals."

In the debate over the role of IRBs in ethnographic research, there are some who believe that such research should be removed from IRB authority entirely. Lederman says she respects that argument. However, she suspects that if IRBs didn't review ethnographic proposals, funding agencies likely would require some other entity to do so.

"I doubt that an IRB-like system involving prior review would be workable within the framework of national professional associations," she says.

Lederman does believe that IRB review of ethnography could be improved at many institutions by creating subcommittees, made up of ethnographers from various fields, to review the proposals. She suggests that this model for ethnographic reviews might also be feasible if ethnography was exempted from IRB reviews.

Depending upon the makeup of the university, membership could be drawn from anthropology, sociology, education, nursing, medicine, political science or even economics since ethnographic subcultures exist in all those fields.

"If you collect the ethnographers together to review ethnographic proposals, a lot of the issues would not have to be explained over and over again," she says. "Researchers would know that if their research relies on participant observation, they should submit it to this subcommittee."

As the subcommittee reviewed proposals, it could help modify the basic IRB form to accommodate the particular needs of participant-observation fieldwork.

"It would engender helpful changes organically in its review process," Lederman says. ■

Dealing with ethnographic issues

If both IRBs and researchers give a little, you can protect subjects and meet the needs of ethnographers

When IRBs encounter ethnography proposals, their concerns—and requests for change—tend to fall into a few key areas.

Lack of detail in the questions to be asked and in the informed consent process can leave a proposal in limbo.

But those with a foot in both worlds say there are steps that ethnographers and IRBs can take to ensure appropriate protection of informants while still giving the ethnographers the flexibility they need.

Specifying questions

While IRBs want to see specific lists of questions

that will be asked of informants, ethnographers generally don't develop questions until they've spent time in the communities they're studying.

As an example, **Rena Lederman**, PhD, associate professor of anthropology at Princeton University, Princeton, NJ, described fieldwork she did in New Guinea earlier in her career.

"I was interested in how large-scale events were organized in decentralized political systems, based on (her) pre-fieldwork reading," she says. "But I couldn't presume to phrase questions in ways that would be meaningful locally until I'd been in my field community for a while.

"While I did eventually conduct informal interviews, the largest part of my research involved in-context conversations and both observing and participating in everyday social life, the peculiarities of which I could not have planned in advance," Lederman says.

Ethnographer **Edward Bruner**, PhD, professor emeritus of anthropology at the University of Illinois at Urbana-Champaign, IL, says that with this type of this research model, the focus of a study can change, and change again over its course.

"We keep in touch with the people we study and we keep reevaluating the study and keep telling them what we think we're finding and we keep recording their reactions to it," he says. "This can go on for a year. It's so different from the biomedical model. And this is what I think is the cause of all the difficulties we've had with IRBs."

Lederman says researchers might address this IRB concern by describing their study's rationale and giving examples of how the researcher would respond if a topic of interest comes up in conversation with informants.

For its part, Lederman says, the board would have to understand that the discovery process in ethnographic fieldwork is inherently open-ended, so the researcher's initial topic of interest at the time of the IRB proposal won't be able to exhaustively describe the final research.

Lederman says this process has worked well on her own IRB.

Informed consent — written or oral?

Ethnographers have long argued that informed consent documents are a bad fit with field research, where, for example, researchers may be working with tribes that are not literate.

Lederman says that the informed consent document itself may pose a risk to informants in certain situations, where it serves as the only evidence of their participation in a study. In order to preserve confidentiality, researchers often will

use pseudonyms or numbers in their notes to avoid linking the data to particular people. So the only place a person's name might be available is on an informed consent document.

This might pose a real danger, for example, in human rights research, or in studies that look at illegal activity or stigmatized conditions such as AIDS.

"In field settings, consent forms can be confiscated by local authorities, they can be stolen," Lederman says. "And if they're the only items that associate named individuals with your project, they themselves can constitute a breach of confidentiality."

Moreover, she says, the emphasis on a consent form misrepresents what informed consent entails in ethnographic research, where consent is a long process of gaining trust and access to people.

"In a more conventional experimental style of social research, access means you're negotiating with somebody about coming into the lab or sitting down for an interview," Lederman says. "Access is more like an event. 'Here's exactly what'll happen: Will you do it?' 'Yes I will.' 'Sign this form and let's get going.'"

"In ethnography, access is really something that's worked on over the course of the whole research. You're always developing relationships and gaining access to people. As people get to know you better, they're able to judge in new ways what to tell you or show you, and what to allow you to participate with them in."

Lederman notes that consent forms themselves are not required by the Common Rule, which allows for informants to give oral consent. But forms often are required by IRBs because that addresses their own need to document compliance procedures.

Lederman says her IRB has been willing to forego written consent forms in circumstances where they're inappropriate to the cultural situation. Donald K. Robotham, PhD, a professor of anthropology and IRB member at the City University of New York in New York City, says his own IRB actually has insisted on oral consent when they thought informants in a foreign country might be at risk from a written form.

But Lederman says in cases where there will be no written consent, ethnographers need to explain to the IRB the process they will follow in obtaining consent and in helping informants fully understand what the researcher is doing and the risks of participating.

She says researchers — especially novice fieldworkers — need to show that their research preparation has included consultations with scholars who've worked in field circumstances similar to the

planned study and who can offer practical advice.

"IRBs need information about this practical preparation," she says. "People don't always explain that well enough the first time around."

And Robotham says IRBs should still ask tough questions about how researchers will ensure that consent is truly voluntary and that the research doesn't put informants at undue risk.

In some cultures, for example, a researcher might seek the oral consent of a village elder before pursuing any work in the village.

"How does one ensure that the elders do not coerce or bring undue pressure on villagers to participate in the study?" he asks. "Or, on the other hand, how does one protect poor informants in a small village from pressure by village or state authorities?"

"My IRB has discussed such issues in at least two cases I am familiar with and mainly focused on specifics of the interviews and the village power context, as well as ensuring the security of the data." ■

Be creative in seeking out unaffiliated members

Once you've found them, provide special training and make them feel like part of the group

Want to attract and retain good nonscientific, unaffiliated IRB members? Cast your net wider for interested people, train them well and nurture them carefully.

Emily E. Anderson, MPH, a PhD candidate in healthcare ethics at St. Louis University, Missouri, says that after interviewing more than a dozen lay IRB members, she thinks IRBs should do a better job of choosing and preparing nonscientist and unaffiliated members for their roles.

Her findings were published earlier this year in the journal *Accountability in Research*.

Anderson says her own experiences serving on one IRB, and watching others, showed her that every board has a unique personality, which can make it harder or easier for a lay member to contribute.

"Having a different set of personalities, having a different chair, different levels of administrative support, different ways of running meetings — all of those things contribute to an outsider's ability to raise concerns," she says.

Anderson says her focus on IRBs was an outgrowth of a larger interest in community participation in research. As part of her PhD program, she participated on an IRB as an outside member. That experience got her thinking about the challenge of

selecting nonscientist and unaffiliated members who can contribute to an IRB.

"People identified it as a problem, but in terms of really doing any kind of searching into what kinds of people are serving in these roles or how IRBs can identify them, there was very little on that," she says.

Anderson identified IRBs in two Midwestern cities and sent word to the IRBs that she was interested in speaking with lay members. She says she very quickly was contacted by the 16 people she ended up using in her qualitative study.

"People were very willing to talk to me — very eager to talk and very accommodating," she says. "The people I interviewed were probably the more participatory members. Someone who just shows up at meetings and doesn't do anything is probably not going to contact me to talk about their experiences."

The group of 16 represented eleven institutions, including universities, hospitals, a Veterans Administration facility and one research organization. Some were members of more than one IRB.

Most recruited personally

Anderson chose to interview only members who were both nonscientists and unaffiliated — not always easy to find on an IRB, she says. In many cases, she notes, IRBs have "nonscientist" members who are affiliated with the institution, and "unaffiliated" members who are scientists.

Among her sample, one member was a pharmacist, but she included him because he was not a researcher and served on a social-behavioral IRB, which she felt made his experiences more pertinent.

Anderson asked them about their experiences of being selected and trained for the IRB, as well as their attitudes about how they were treated.

From their answers, and from her own observations of various IRBs, Anderson suggests that institutions can do a better job of recruiting, training and nurturing lay members:

- **Recruitment** - Most nonscientist, unaffiliated members interviewed by Anderson were initially asked to serve on an IRB by someone they knew. In one case, a woman met an IRB member because their children went to school together. Many were asked to become lay members after having previously worked for the university or actually serving on or being employed by the IRB.

Three of the members surveyed said they approached the IRB after hearing about a need for community members. One woman, recently retired, says she was looking for a chance to volunteer "where I didn't have to stuff envelopes . . . and I might be able to use my brain."