

THOMSON  
 AMERICAN HEALTH  
CONSULTANTS

## IN THIS ISSUE

- Electronic data system produces information helpful to more efficient staffing
- Central IRBs and other models may be answer to multi-site trial trend
- Q&A: SACHRP chair discusses latest work by committee
- Ethnography and the IRB: Unique research strategy causes difficulty for board review
- Some suggestions for solving problems with ethnographic proposals

### Statement of Financial Disclosure:

Editor Suzanne Koziatek, Editor Melinda Young, Editorial Group Head Lee Landenberger, Managing Editor Leslie Hamlin, Nurse Planner Kay Ball, and Physician Reviewer Alan Sugar, MD, report no consultant, stockholder, speaker's bureau, research, or other financial relationships with companies related to the content in this CE/CME activity.

**SEPTEMBER 2006**

VOL. 6, NO. 9 • (pages 97-108)

## IRB director offers guidelines for running a more efficient office

*Answer is data, data, data*

The first step to improving your IRB office's efficiency is to collect data through a software system that will make sense of files and reports.

Next, make sure the reports include information about staffing levels, committee levels, and other workload issues, suggests **Tanna MacReynold**, CIP, institutional review office assistant director at the Fred Hutchinson Cancer Research Center in Seattle, WA.

"We've enhanced the database, and we've moved to an electronic review for IRBs," MacReynold says.

The electronic system, which the IRB office staff helped design, is called PIRO for Protocol Institutional Review Office, and it's helped considerably in making the office more efficient, MacReynold says.

"Before we had the new database the bulk of our work was expedited reviews, and we had to put together the expedited review agenda, which took one staff person three days to cut and paste the 40-some pages of expedited reviews," MacReynold says. "With the database change and the automated reports, it now takes about 30 seconds."

There also are efficiencies in the form of paperwork: for example, the office has reduced 26 hard copies of information down to one hard copy, and the database captures most of the information, allowing it to be viewed electronically through a Web-based system, MacReynold says.

"So it can be reviewed anywhere, so long as people have access to the Internet," MacReynold says. "They can go to a secure Web site and post real-time comments."

These comments from IRB members are tracked prior to the meeting, helping to inform members and facilitate discussions that will expedite the IRB's response, MacReynold adds.

IRB meetings are held monthly in the traditional face-to-face way, but the Internet commentary before the meetings is one of the electronic system's biggest benefits, she says.

Another major change that has facilitated more efficient work flow is an office reconfiguration. This is where data played an essential role.

Rather than just looking at the office's study output and basing

**NOW AVAILABLE ON-LINE: [www.ahcpub.com/online.html](http://www.ahcpub.com/online.html)**  
**Call (800) 688-2421 for details.**

staffing needs on that number, MacReynold looks at how many activities the IRB office performs over a 12-month period.

These include the following:

- How many modifications and revisions are there?
- How many annual reviews?
- How many adverse events?

**IRB Advisor** (ISSN 1535-2064) is published monthly by Thomson American Health Consultants, 3525 Piedmont Road, Building Six, Suite 400, Atlanta, GA 30305. Telephone: (404) 262-7436. Application to mail at periodicals postage rates is pending at Atlanta, GA 30304. POSTMASTER: Send address changes to **IRB Advisor**, P.O. Box 740059, Atlanta, GA 30374.

Thomson American Health Consultants is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

Thomson American Health Consultants designates this educational activity for a maximum of *18 AMA PRA Category 1 Credits™*. Physicians should only claim credit commensurate with the extent of their participation in the activity.

Thomson American Health Consultants is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation.

AHC also is approved as a provider by the California Board of Registered Nursing, provider number CEP10864. This activity is approved for 18 nursing contact hours.

This activity is intended for clinical trial research physicians and nurses. It is effective for 36 months from publication date.

Opinions expressed are not necessarily those of this publication. Mention of products or services does not constitute endorsement. Clinical, legal, tax, and other comments are offered for general guidance only; professional counsel should be sought for specific situations.

#### Subscriber Information

**Customer Service:** (800) 688-2421 or fax (800) 284-3291, [ahc.customerservice@thomson.com](mailto:ahc.customerservice@thomson.com). **Hours of operation:** 8:30 a.m. - 6 p.m. Monday-Thursday; 8:30 a.m.- 4:30 p.m. Friday.

**Subscription rates:** U.S.A., one year (12 issues), \$389. Outside U.S., add \$30 per year, total prepaid in U.S. funds. Discounts are available for multiple subscriptions. For pricing information, call Steve Vance at (404) 262-5511. **Back issues**, when available, are \$65 each. (GST registration number R128870672.)

To reproduce for promotional purposes, please contact: Stephen Vance, *Telephone:* (800) 688-2421, ext. 5511  
• *Fax:* (800) 284-3291 • *E-mail:* [stephen.vance@thomson.com](mailto:stephen.vance@thomson.com)  
• *Address:* 3525 Piedmont Road, Building 6, Suite 400, Atlanta, GA 30305

**Editors:** Suzanne Koziatek and Melinda Young.  
**Vice President/Group Publisher:** Brenda Mooney, (404) 262-5403, ([brenda.mooney@thomson.com](mailto:brenda.mooney@thomson.com)).  
**Editorial Group Head:** Lee Landenberger, ([lee.landenberger@thomson.com](mailto:lee.landenberger@thomson.com)).  
**Managing Editor:** Leslie Hamlin, (404) 262-5416, ([leslie.hamlin@thomson.com](mailto:leslie.hamlin@thomson.com)).

Copyright © 2006 by Thomson American Health Consultants. **IRB Advisor** is a registered trademark of Thomson American Health Consultants. The trademark **IRB Advisor** is used herein under license. All rights reserved.



#### Editorial Questions

Questions or comments?  
Call Leslie Hamlin at (404) 262-5431.

- How many protocol violations, deviations, and other miscellaneous items?

MacReynold estimates necessary staffing levels based on the volume of these various office tasks over a five-year period.

"So I entered in the activities I wanted to check, and instead of just seeing that we had 1,200 protocols for 2005, I saw that we had 4,852 activities," MacReynold explains.

Then MacReynold could divide the activities by full-time equivalent (FTE) positions to come up with a formula of X number of activities and Y number of studies per FTE.

Since anecdotal evidence suggests the office's workload was manageable, but not distributed as efficiently as possible, MacReynold had data suggesting the number of activities per FTE that would be suitable. However, there still was room for improvement.

"It's not like I have a magic number that's right, but I can say that we switched things around, looked at different numbers, and then we came up with a new arrangement where we have an analyst and an assistant assigned to each committee," MacReynold says.

The analyst takes the IRB's meeting minutes, writes letters, and interacts with investigators, helping them make protocol improvements pre-review, she says.

The administrative assistant helps with processing paperwork after IRB approval and also does filing, and handles other tasks, MacReynold says.

As the operations person, MacReynold helps bring consistency to reviews between the center's several IRBs.

"If I'm sitting in on two or three committees, and one says, 'We should do it this way,' I might tell them that the other committee handled it a little differently," MacReynold explains. "So I bring consistency to the committees, and I bring institutional requirements and help with regulatory issues."

Another full-time staff person is the consent editor who helps investigators with their consents after they've written these, she adds.

An IRB also should help an institution decide when it's time to expand to additional IRB committees, based on the data about the workload.

In 2001, the center had about 700 studies, which were handled by two IRBs, MacReynold says.

When the number of studies expanded to 1,200, it was time to add a third IRB, she says.

"It was too much to ask each committee to review 600 protocols a piece," MacReynold says.

"This was a different calculation; we already were growing our staff based on the activity level, but we weren't growing the committee."

Further calculations based on the data suggested it was a serious deficit to continue IRB activities with only two IRBs, she adds.

Once an IRB office has a handle on the data and can pull up the information that's necessary to tweak improvements and efficiencies, then it's a matter of managing the numbers and making adjustments, as needed, MacReynold says.

"Now that I have worked out these numbers, and we seem to be at a manageable workload with the numbers we have, then each year I will run the numbers, and the activities increase, I will compare this data to how manageable the workload feels to the staff," she explains.

If she were pressed to give a rule by thumb, then she would say that 157 protocols per FTE appear to be reasonable. Then you multiply the protocols by three to equal the average number of activities, MacReynold says.

Another part of the information that MacReynold checks is the growth rate of the protocols versus the growth rate of activities.

"I want to see if activities are growing as fast as the protocols," she says. "If you just go by the protocols, you might put in for another FTE, but you won't know if it relates to your workload."

By following this comparison of growth rates, MacReynold found that the protocols were growing at a faster rate than the activities, so that provided a little more depth to her analysis of whether additional staff would be required.

Another factor is whether the protocols have greater proportions of high versus low risk, which could translate into more work versus less work, she says.

"Fifty protocols might mean something different between two institutions," MacReynold says.

"The other thing I did find was there is a whole lot of workload influences between the activities, and people have to consider these," she notes. "When you really get down to what the staff are doing, which is what I did, then there's all this hidden stuff that aren't accounted for."

For example, IRB office staff spend time on training IRB members, research staff, auditing, assisting subcommittees, and keeping up the Web site, and that time should be part of the equation, MacReynold says.

Nonetheless, the electronic system's implementation has resulted in staff work improvements.

Since the software system made the entire office more efficient, staff members have had time to do more substantive reviews and assessments, rather than spend their time attending to paperwork issues, she says.

"They can shift their knowledge and skills to looking at regulations, educating investigators, and those sorts of things," MacReynold says.

The software has become popular through word-by-mouth, although it is not sold or distributed publicly.

"At every single IRB conference, people ask if they can buy our software," MacReynold says. "It may be marketed in the future." ■

## Sharing of IRB approvals raises questions, concerns

*OHRP analyst comments on trend*

As times change and evolve, so do IRBs and, ultimately, IRB guidelines and rules. Lately, the evolution of IRBs can be seen in the trend of an increasing number of multi-site studies.

Changes in how IRBs handle multi-site studies have been slower to evolve.

"Historically, the procedure was to have the study reviewed by the IRB for each site," says Glen Drew, MS, JD, health policy analyst for the Office for Human Research Protections (OHRP), Department of Health and Human Services in Rockville, MD.

"The regulations provide for cooperative research agreements where institutions recognize the review of the IRB at another institution and accept that review as being verification that human subject's protection requirements are being provided," Drew explains. "So the regulations have long provided for that, but it is often not utilized by institutions."

Many institutions have continued to want all research to be reviewed by their own IRB, Drew notes.

Yet, as the number of multi-site trials increases, the reliance on individual IRB review for each site is seen by many as an unnecessary burden, Drew says.

OHRP officials and other government officials are considering holding a public conference later this year to discuss the options and alternatives available to individual IRB review by all institutions involved in a multi-site study, Drew says.

In discussions that have already taken place, offi-

cials agree that it's desirable to encourage an increase in alternatives to individual IRB reviews, he adds.

"Many institutions are reluctant to give up the control they feel they exercise through their own IRB," Drew says. "I think one of the matters to be addressed in coming days, perhaps coming years, is how to relieve concerns the individual institutions might have."

For example, a chief concern involves liability in the event a problem occurs with the research, Drew says.

"If there's an adverse event or an unexpected outcome in the research, then institutions don't want to risk some level of liability for that outcome without having exercised the control of being involved in the review of the research," Drew says.

One solution to this concern is greater education and knowledge about cooperative arrangements now in place, he says.

For example, the Biomedical Research Alliance of New York is a group of academic institutions in the Northeast that has decided that an IRB review by any one of the involved institutions would be recognized and accepted by all of the other institutions, Drew explains.

"There are a couple of other consortia in operation," Drew says. "The National Cancer Institute has a pilot project that has grown over time and operates a central IRB for adult oncology research and for pediatric oncology research."

The arrangement permits local IRBs to rely entirely on the central IRB's review or to rely partially on the central IRB's review and retain their own local context and/or informed consent review, he says.

Gaining greater acceptance for central IRB review may occur when it's no longer a matter of institutional pride to favor one's own IRB's judgment over other IRBs' judgment, Drew suggests.

"Certainly there are possibilities for having test cases in which you have the same protocol reviewed by multiple IRBs and compare the conclusions they draw," Drew says.

"Some IRBs may find a protocol acceptable as written, while others would require modifications, and these requirements may be in full alignment or vary across the IRBs," he adds. "Seeing results of each other's work may give or prevent some confidence in the work of other IRBs."

Other confidence-building measures include inviting other IRB members to visit an IRB meeting as guests, he says.

Sponsors often see the model of a central IRB as desirable because it may prevent delays, Drew says.

"It reduces the overall delay because it eliminates the need to reconcile any differences between what different IRBs say," Drew says. "There's no need to send consent language back and forth between different IRBs."

The people most impacted by multiple IRB reviews are investigators who can't get their studies going and sponsors who want to move their investigational product more quickly to market, he adds.

OHRP has been trying to reduce and eliminate unnecessary burdens on the research enterprise, while maintaining protections for subjects, Drew says.

Some people in the research industry think OHRP frowns on the practice of central IRB review, but the truth is that such reviews are perfectly acceptable, Drew says.

"I think there's a need for increasing the awareness of the acceptability of such practices," he says. "Where they can increase efficiency without compromising protections, they are to be encouraged, and that's why we're working with other federal agencies to increase awareness that the practice is perfectly acceptable so long as protections are not compromised." ■

## **SACHRP chair updates *IRB Advisor* on IRB regulations**

*Ernest Prentice gives Q&A interview*

*[Editor's note: In this question-and-answer interview, Ernest Prentice, PhD, associate vice chancellor for academic affairs at the University of Nebraska Medical Center in Omaha, NE, and the chair of the Secretary's Advisory Committee on Human Research Protections (SACHRP) for the U.S. Department of Health and Human Services (HHS) discusses with *IRB Advisor* SACHRP's work through mid-July, 2006, and what is expected later this year.]*

***IRB Advisor:*** What are some the latest issues and things discussed and decided by SACHRP?

**Prentice:** The subcommittee of research involving children has been meeting continuously since we began our deliberations. And they have produced a series of reports.

They've had all of their recommendations to date accepted by the [HHS] Secretary. One set of recommendations has already been implemented by OHRP, and the other recommendations are waiting, so we have a complete set which will

occur hopefully at our August meeting, where we're going to be able to provide a complete set of recommendations about how Subpart D should be interpreted and applied by IRBs so we have what we refer to as consistent protection of children involved in research, so that we neither unduly prohibit their participation, nor do we exploit them in any way.

We're very concerned about having appropriate, additional protections in place. So that subcommittee will complete its work as of the August SACHRP meeting.

**IRB Advisor:** What are some of the recommendations that will be considered and probably will end up in the document?

**Prentice:** One subcommittee is looking at the issue of additional protections for children. The problem with additional protections for children is that there are a whole lot of terms in there that IRBs have never understood before, things like what are the definitions of minimal risk. Should minimal risk be tied to the daily life the individual research subject, which is called a relative standard, or should it be tied to the daily life of healthy children? All of the protections built into subpart D rest upon that definition, as to whether or not there is the prospect of direct subject benefit. So that's a threshold level of risk that determines what additional protections should be in place. So it's extremely important that IRBs have an appropriate way to interpret minimal risk and apply minimal risk. So we have advocated the utilization of what we call a uniform standard that is tied to the daily life of a healthy child living in a safe environment, as an example. We also look at other terms in subpart D which were problematic for IRBs to interpret over the years. And "a minor increase over minimal risk." No one ever knew what that meant. "Disorder or condition." That was very confusing to IRBs. There's a requirement that research be of vital importance when it's to understand or amelioration of subject's disorder or condition when the subject is greater than minimal risk and there is no prospect of direct subject benefit. Well, nobody really understood what "vitally important" meant. So we spent days and days and days with a group of very brilliant people who were experts in the field, basically discussing how to interpret these terms that were included in subpart D.

**IRB Advisor:** Will you publish your recommendations?

**Prentice:** Everything we do is public. It's all published on the Web site. We don't publish the

letter, but the recommendations that are passed at the meeting are a public transcript, available to the public.

The fourth subcommittee, which is ongoing, is what we call our subpart A subcommittee. The subpart A subcommittee is looking all aspects of subpart A, and they're trying to determine how best to interpret some of the terms, including "minimal risk." How should minimal risk be interpreted for research involving adults? Should it be tied also to the healthy person standard? This is our newest subcommittee, so we have not generated any letters to the Secretary.

The subcommittee also is looking at expedited review: Should the list be expanded? Should it be clarified? We're looking at continuing review: should continuing review be required to be performed no less often than annually? Or should you have a longer interval for minimal risk research? We're looking at concepts like when does a study actually end; that seems to be unclear as to when continuing end should be able to cease. Do you continue to perform continuing review as long as subjects are in follow-up? Do you perform continuing review as long as the data is in the analysis phase? So we're looking at things of that nature.

One of the problems with the current guidance issued by OHRP and FDA is that if an investigator fails to get their continuing review application to the IRB and it's not re-reviewed and re-approved by the IRB approval expiration date, all research activities have to halt unless it's in the best interest of the research subjects to continue, in which case the IRB can make an exception. One of our problems is investigators sometimes wait until the last minute, and if you are reviewing a continuing review application at an IRB meeting, and you have any questions or require even minor clarifications and you're up against that IRB approval date, you have to stop the research.

So we're recommending that if the continuing review is already underway by the IRB and there are no significant problems that are identified then we feel as though there ought to be a 30-day window. Have the IRB expiration date when the IRB can complete its review without halting the research. So these are some of the issues that the subpart A subcommittee is grappling with and, again, these are not recommendations passed by SACHRP, these are issues considered by the subpart A, subcommittee which will eventually result in recommendations produced by SACHRP, which will go on to the Secretary.

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 organizationally 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 field-workers — 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."

The members themselves suggested that a bachelor's degree was an important asset, and others suggested backgrounds in professions such as law, science or the ministry. A few members who are lawyers say they were recruited not for their legal qualifications but because their IRBs thought they'd bring analytical skills to the table, Anderson says.

But Anderson herself would like to see IRBs become more creative in seeking out lay members, in order to achieve more diversity on the board. She notes that her sample, like others of lay IRB members, was overwhelmingly white, educated and professional.

"[IRBs] really need to avoid selecting them just based on convenience," she says. "Try to find people who are going to be good because of their personal qualities and skills and not just because they happen to already be known and easy to find. Are they going to contribute anything, or are they just the neighbor of the provost and doing somebody a favor?"

Anderson says she believes having only one or two lay members on a board makes it even harder to achieve diversity.

"You can't expect one person to be reading the protocol wearing multiple hats at the same time," she says. "Having more than one person to fill these roles or having different combinations of people who are nonaffiliated and/or nonscientist, is one way to bring diversity to an IRB."

Anderson notes that as IRBs have gotten larger, the number of lay members has stayed about the same. She sees that as a missed opportunity for IRBs to diversify.

"There are IRBs who will have 25 members and they'll still only have one or two nonaffiliated/nonscientist members."

• Training — Once lay members were selected, the training they received varied greatly from one institution to another. Some reported no formal training at all, while others took Web-based programs or attended one-on-one sessions with an IRB staff member.

Most said they were faced with an overwhelming amount of material, and that their real education came on the job. They complained that mate-

rial was presented in a disorganized way, making it hard to know what was most important in reviewing a protocol.

Anderson notes that lay members reported that they often received exactly the same training as scientific members, who come to the IRB with much more research experience.

"People who are nonaffiliated, nonscientist members need special training," she says. "It's not impossible to bring them up to speed, but you can't just throw them in. Common sense tells you that training for someone who's been a researcher for 15 years and training for someone who doesn't know anything about research should be different."

She says members benefited from being able to observe actual IRB meetings before joining the board, so that they could observe protocols being reviewed without the pressure of having to participate.

### ***Observing 'social graces'***

Nurturing — While most of the lay members told Anderson they were treated well and respected by other members, many did feel intimidated sharing the IRB table with professors and scientists.

Anderson says it's possible to ease that discomfort by taking small steps to make the new members feel like a part of the group.

"Some people mentioned that they weren't even introduced to the committee and that the other members were not introduced to them," she says. "So there were people who'd been serving for a year and they weren't even sure who everyone was. They weren't sure that everyone knew who they were."

"That just seems like basic Social Graces 101. If you're having a committee of people and you have a new member, you introduce them. Especially if it's someone from the outside, who will perceive that they're on a different level from everyone else."

She says members told her they really appreciated small gestures like being complimented when they made a good point, or being contacted by the administrator after the meeting to see if the member had questions.

"Things like that can help people feel more comfortable expressing any concerns that they have, which is sort of the point of having those people there," she says. ■

## ***COMING IN FUTURE MONTHS***

■ How much should an IRB limit interviews involving children and parental mental illness?

■ Improve handling of mandatory reporting laws

■ Experts discuss the use of pregnant women in research

■ Research subjects to assess the effectiveness of human subjects protection training

■ Use quality improvement methods to enhance IRB operations

## EDITORIAL ADVISORY BOARD

**Alan M. Sugar, MD**  
Chairman, New England  
Institutional Review Board  
Professor of Medicine  
Boston University School  
of Medicine

**Kay Ball, RN, CNOR, FAAN**  
Perioperative  
Consultant/Educator  
K & D Medical  
Lewis Center, OH

**Paul W. Goebel Jr., CIP**  
President  
Paul W. Goebel Consulting Inc.  
Monrovia, MD

**Elizabeth E. Hill, RN, DNSc**  
Assistant Professor  
Director, Clinical Research  
Management Program  
Duke University School  
of Nursing  
Durham, NC

**John Isidor, JD**  
CEO  
Schulman Associates IRB  
Cincinnati

**Robert M. Nelson, MD, PhD**  
Associate Professor of  
Anesthesia and Pediatrics  
The Children's Hospital  
of Philadelphia

**Jeremy Sugarman**  
MD, MPH, MA  
Harvey M. Meyerhoff  
Professor of Bioethics  
and Medicine  
Phoebe R. Berman Bioethics  
Institute and Department  
of Medicine

Johns Hopkins University  
Baltimore

**J. Mark Waxman, JD**  
Partner  
Foley & Lardner  
Boston

## CE/CME questions

13. True or False: Federal human subjects research regulations provide for cooperative research agreements where institutions recognize the review of the IRB at another institution and accept that review as being verification those human subjects requirements are provided.

- A. True  
B. False

14. According to the chair of the Secretary's Advisory Committee on Human Research Protections (SACHRP) of DHHS, which of the following is one of the problems with current OHRP and FDA regulations, regarding continuing review applications to IRBs?

- A. Continuing reviews by IRBs require too much paperwork and therefore are an inefficient use of IRB time.  
B. Continuing reviews are used too liberally by IRBs, and guidelines for more accurate use of them need to be written.  
C. If an investigator fails to get their continuing review application to the IRB and it's not re-reviewed and reapproved by the IRB approval expiration date, all research activities have to halt unless it's in the best interest of the research subjects to continue and the IRB makes an exception.  
D. None of the above.

15. Which of these departments might be tapped for an IRB subcommittee to review ethnographic proposals?

- A. Ethnography and sociology  
B. Medicine and nursing  
C. Economics and political science  
D. Potentially all of them, depending on the university

16. Because nonscientist, unaffiliated IRB members will serve on the same board as scientific members, they need exactly the same training in human subjects protection.

- A. True  
B. False

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