IRB ADVISOR

Your Practical Guide To Institutional Review Board Management

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IN THIS ISSUE

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Katrina two years later: What have we actually learned?

New Orleans IRBs hold lessons about disaster preparedness

Two years after Hurricane Katrina ravaged the Gulf Coast and caused a mass evacuation of New Orleans, research institutions in the city are still recovering.

They're coping with the long-term reverberations from the disaster — the flight out of the city of much of its population, including a number of university employees, and the loss of studies. And of course, they're preparing for the next potential hurricane, with disaster plans that have been honed and updated by their experiences with Katrina.

Kenneth Kratz, PhD, director of the Office of Research Services at Louisiana State University's Health Sciences Center in New Orleans, says the lessons in emergency preparedness that his IRB learned from Katrina are applicable elsewhere — not just along hurricane-prone coastal areas.

The problems uncovered in the wake of the disaster, including the loss of contact with many research subjects, have implications for any IRB threatened with a large-scale natural or man-made disaster.

"An institution could face all kinds of disasters, from tornadoes to hurricanes to floods," Kratz says. "I think all institutions with a human subjects protection program really have an obligation to have some kind of preparation for this. That's what I've been advising people when they contact me."

Many challenges

In the days and weeks after Katrina, Kratz and **Mark James**, PhD, chair of the biomedical IRB at Tulane University's Health Sciences Center in New Orleans, both faced similar challenges:

- finding and communicating with principal investigators, as well as trying to determine what had happened to thousands of subjects signed up for clinical trials;
- finding and communicating with their own IRB members and staff, many of whom had scattered across the country;
- gaining access to records and to their offices, often hampered by

flood waters and law enforcement restrictions on accessing university buildings;

• reinstating a schedule of meetings and reviews to deal not only with existing studies, but with new proposals, many by faculty members wishing to study the effects of the hurricane.

Communications were sketchy — it was difficult to get phone service not just in New Orleans, but even as far away as Baton Rouge. E-mail access was debilitated as well — Kratz says that for the first few weeks, while LSU's servers were down, his staff communicated by text messaging.

LSU's IRB moved to the university's Baton Rouge campus and operated from there for about six months. Tulane's IRB director evacuated to North Carolina, and that IRB held its first few meetings after the hurricane via teleconference with members who were spread across the country.

One of the most critical challenges facing Kratz and James since the hurricane has been trying to re-establish contact with thousands of research subjects, including those on clinical trials being treated for serious diseases, such as cancer and diabetes.

Kratz says that at LSU's Cancer Center, investigators have been able to track down about 70 percent of subjects who were in their trials two years ago. The university used existing contact information, mail forwarding, newspaper ads and Social Security death information to get that far.

"There still remains a relatively large number of people that were in oncology trials and other trials we had open [who are still unaccounted for]," he says. "A significant number have not been relocated."

"The idea that we lost contact with those people really was disturbing for us, obviously," he says. "People were receiving treatments, particularly experimental kinds of drugs, which you shouldn't just terminate immediately because of potential consequences. Or people who moved to, say Houston, and went to see another physician because they had some sort of disorder — that physician would not know what their treatment regimen might have been. This created a situation for people where their continued treatment was compromised. "We've lost a lot of sleep over that."

James says his institution's investigators, too, were hampered in their attempts to locate all their subjects.

"There's a lot of PIs that are still frustrated that we have not completely contacted 100 percent of their participants," he says. "They're scratching their heads trying to figure out what can we do to contact these people."

Since Katrina, both LSU and Tulane have instituted new disaster preparedness plans that emphasize staying in contact with subjects.

LSU's plan instructs PIs to give every subject in existing trials, and those recruited for new trials, a letter informing them of a toll-free tele-

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phone number they could call in an emergency. Subjects could leave contact information with the call center in order to be put in touch with someone from their study team.

Both LSU and Tulane also have required investigators to issue new subjects wallet-sized cards they can carry with them at all times, with information about their trial and about emergency contacts.

"That makes it a little easier for subjects," Kratz says. "They don't have to find a letter someplace and remember it. They just have to stick this in their wallet or purse and have it with them."

The LSU and Tulane disaster plans also call for increased contact information about IRB staff and PIs, including alternate contact numbers in the event of another evacuation.

James says Tulane's IRB director develops a disaster communication list at the beginning of each hurricane season (the annual Atlantic hurricane season runs from June 1 to Nov. 30), with updated contact information for IRB members. Elsewhere in the university, units establish their own communication trees.

He says the IRB also expects investigators to include emergency plans with any applications for greater-than-minimal risk studies, and to include information about evacuation procedures in informed consent for such studies.

Smaller staffs, changing studies

Even while coping with the challenges of communications and running offices in a disaster mode, both universities suffered an immediate loss of human subjects protection staff.

"Right after the hurricane I lost three of my [five] coordinators," Kratz says. "Two of them evacuated and decided not to return to Louisiana. Another one quit and took a job in New Mexico, leaving me with two full-time staff." Kratz also lost the help of three student workers, and the assistant director of his office was reassigned to another post at LSU.

"That left us pretty lean for quite awhile," he says. "In the last six months or so, I've been able to hire back another coordinator, so I'm up to three full-time coordinators, and I finally got the three student workers back."

At Tulane, the IRB director herself, who also chaired the IRB, decided not to return. The Tulane human subjects protection office was restructured, separating the two jobs, and James was appointed chair of the IRB.

The Office for Human Research Protection worked under an interim director until April 2006, when a permanent director was chosen.

James says in the months after the disaster, the office lost two staffers because of financial considerations.

"Basically, we did have an adjustment period where we had to rearrange staff," he says. "We're just now beginning to get to the point where we're working with an intact, complete office."

According to US Census estimates, the population of New Orleans is less than half what it was before Katrina. In addition, many of the city's major public and private hospitals were closed, and not all have reopened. As a result, the number of new studies being opened in the city has dropped substantially.

Kratz says that before the storm, LSU's office was managing more than 1,200 studies, about half of them greater than minimal risk. Now, he says, that number is down to about 650, about 220 of which are greater than minimal risk.

In addition, a number of faculty members left, some because they moved to other institutions and some because the university reduced faculty after the storm. Those factors led to the deactivation of one board and a reduction in members on the other.

"We reduced the size of the board from 18 permanent members to 11, which was OK because we still maintained the expertise that we needed on that one board," Kratz says. "And we were reviewing fewer studies, of course."

Tulane, which previously was operating with two review teams, is down to one, and has reduced the number of meetings from two monthly to one, as well, James says.

James says that the Tulane IRB's workload has changed, with more of an emphasis on the university's existing international public health research program.

One IRB a little farther afield saw a sudden and dramatic increase in the number of studies submitted in the days and months after Katrina. The social-behavioral IRB at LSU's Baton Rouge campus was inundated by researchers wanting to conduct surveys of the evacuating New Orleans residents, many of whom initially decamped to Baton Rouge.

At first, says **Robert Mathews**, PhD, chair of the social-behavioral IRB, he demanded full board studies of all such proposals, in effect, treating all of the evacuees as a vulnerable population.

"I really was over-conservative — I had no experience with this sort of thing," Mathews says. "Everything, initially, in the first month or so, was going to the full IRB, so we had to have lots of meetings."

After the first few weeks when he realized most of the proposals were fairly low risk, he began to handle some of them through expedited, and then exempt, reviews.

"Some of the stuff was really mild — asking about businesses, asking people where they want to relocate," Mathews says. "And as we started to realize we weren't getting any complaints, I felt like we could handle a lot of it through expedited reviews. And I even started exempting some routine types of surveys again." ■

Access Tulane University IRB's emergency plan at http://www.irb.tulane.edu/emergency_plan.htm

Disaster management tips from the front lines

Technology, regulatory agencies can help during a disaster

While a devastating Category 5 hurricane may not be a realistic threat to your IRB's operations, there are still a number of disaster scenarios that could cause evacuations and region-wide disruptions in communications — everything from earthquakes and flooding to potential Sept. 11-style terrorist attacks.

Those who manned the front lines in Katrina say there are some smart steps every IRB can take to better prepare for such a catastrophe and rebound from it more quickly:

• **Rely on technology, including the Internet —** While land-line and cell phone communications may be disrupted for a large area around the disaster, technology can provide some useful workarounds. IRBs at Tulane and Louisiana State universities used text-messaging, E-mail and teleconferencing to keep in touch and restart IRB operations in the days and months after Katrina hit.

Kenneth Kratz, PhD, director of the Office of Research Services at Louisiana State University's Health Sciences Center in New Orleans, says administration staff all have been issued Blackberry devices, which include wireless E-mail, in order to improve communications in case of emergency.

He points out that during Katrina, he evacuated his office without even remembering to take his laptop computer. "I'll definitely take it next time," Kratz says with a laugh.

Both offices also have Web-based IRB submission systems in place, with emergency data backups that are geographically located far from the New Orleans area.

"You want to be sure the servers you're using are secure — have them someplace remote, so you can get to your information and it's protected," Kratz says.

Contact numbers

• **Get useful emergency contact information from staffers** — In many cases, the emergency telephone numbers on file were useless, since they were for New Orleans addresses which staffers already had fled. Kratz has asked that each LSU IRB staffer and board member provide a contact number outside the region — for example, a relative or close friend in another state who will know where the person is after he or she evacuates the city, and update the numbers regularly.

At Tulane, the IRB director provides an updated communication list at the beginning of each annual hurricane season, says **Mark James**, PhD, chair of the biomedical IRB at Tulane University's Health Sciences Center in New Orleans.

•**Keep in close contact with regulatory agencies and study sponsors** — Tulane's disaster plan authorizes the senior vice president for research to notify the FDA, the federal Office for Human Research Protections, external IRBs of record and study sponsors about Tulane's research situation in a disaster, James says.

"We received good feedback and good concessions, if you will, after the hurricane, in terms of interacting with the FDA, NIH, etc.," he says. "All the regulatory agencies were very responsive in terms of facilitating investigators and their research."

• **Provide cross-training for staff** — Kratz says the immediate loss of IRB staff at LSU after the storm was made easier by the fact that the remaining workers could cover each others' jobs.

"I'm a strong believer in cross-training of everyone, so any of my staff can pick up the processes and continue on with them," he says. "I don't know that anyone would expect that you'd lose that many people that quickly. To keep things up and running, it's important to have everyone cross-trained."

Research with victims

• **Expect researchers to want to speak with victims of the disaster — Robert Mathews**, PhD, chair of the social-behavioral IRB at LSU's Baton Rouge campus, says submissions to his board quadrupled in the months after Katrina hit.

While many of the proposals were innocuous, other researchers wanted to talk to victims about their potentially traumatic experiences in the hurricane. The IRB was very cautious with those requests,

requiring that they be conducted by professionals with mental health experience. They also required that subjects be given contact numbers for psychological counseling, in case they needed it afterward.

"People who study hurricanes, people in engineering get involved," he says. "Suddenly, they're doing research with human subjects and they don't know what their responsibilities are."

Matthews himself attended campus-wide meetings set up to coordinate research, as well as informed faculty about their human subjects protection responsibilities.

Most, he said, showed little resistance to the idea of submitting proposals to the board. There was a little more grumbling about the required 1.5 hours of online human subjects training.

"Since I made a personal appearance there and talked about it, it kind of eased things," he says. "If it had just been a written notice, they might have been more resistant."

Matthews says IRBs should keep in mind that for those traumatized by a disaster, an initial vulnerability may not improve over time.

"When people start to realize they're not going back to their homes, and the government resources are not very good and they're living in these trailer parks, that's when things really start heating up," he says. "A lot of these people are still in trailer camps and will be for a long time." ■

Nurses can add ethical focus to IRB deliberations

Researcher, IRB chair say adding one won't do the trick

For years, IRBs have been urged to improve the diversity of their memberships by adding unaffiliated and nonscientist members; the theory being that lay members bring a greater emphasis on the subject's perspective, and can more easily ensure that subjects understand informed consent.

Now, one sociologist who has studied the activities of IRBs has a provocative suggestion: Stop worrying so much about unaffiliated members. Instead, focus on adding more nurses.

William G. Rothstein, PhD, a professor of sociology at the University of Maryland, Baltimore County, MD, says his survey of IRB members shows nurses were more likely than other groups to rate ethical issues, such as adequate informed consent and protecting subject confidentiality, as "very important" to them personally.

He says nurses were the only group looked at that rated such issues higher than the average of all IRB members. Physicians surveyed consistently rated ethical issues lower in importance than the average, and responses of unaffiliated IRB members were similar to those of other groups represented on the boards, including administrators and pharmacists.

Ironically, both the nurse members and the IRB members, as a group, rated nurses among the least influential groups in committee deliberations, which could dilute their ability to press ethical issues on boards. Rothstein says the answer may lie in adding enough nurses to a board to give them critical mass to make their case.

Rothstein, who himself serves on an IRB, says that when his team began surveying IRB members about their ethical attitudes, he didn't know what to expect.

"We were surprised [by the results], but then we looked at the literature on nurses and their attitudes toward ethical issues, and the two matched very nicely," he says. "The types of ethical issues that IRBs consider are ones that nurses have been shown to be sensitive to in other issues. If the ethical issues had involved sampling or dosage, or types of drugs, I'm not sure nurses would have come out as differently as they did. But IRBs rarely look at issues like that."

Responses from members rated

Rothstein surveyed 284 members of 27 IRBs across the United States. Questionnaires were administered at IRB meetings.

Members were asked for demographic information, as well as to rate the importance of 11 issues, including:

- informing subjects of risks involved in research;
- ensuring adequate attention to ethics and federal human subjects protection regulations;
- ensuring adequate protection of subjects' confidentiality and privacy; and
- ensuring consent forms are written in simple language that subjects can understand.

For every issue, the nurse members rated it as more important than any other group. For example, on informing subjects of risk, 100 percent of nurses found the issue "very important," compared with 86.6 percent of physicians, 86.8 percent of unaffiliated members and 88.7 percent of all members surveyed.

Rothstein says the disparity isn't based on dissimilar ethical values, because each group had nearly identical rankings of all the ethical issues

by importance. He says no differences were found between nurses who did or did not submit research proposals themselves.

Based on these results, Rothstein says it would be more useful for IRBs to recruit more nurses than to spend energy trying to increase the number of unaffiliated members on an IRB.

"It's a waste of time [putting more unaffiliated members on a board]," he says. "First of all, it's hard to find them, and second, they tend to be ignorant of the issues involved. They tend to defer to others, and the others who speak most often and most forcefully are physicians. So I really don't feel it has much of an impact."

Rothstein says that in his experience, researchers on IRBs look at the review process with an eye toward how it might affect their own research in the future.

"They don't want the bar raised higher for any research because it may affect their research," he says. "I've heard this said many times: 'We don't require that,' the implication being if you require it for this other study, then you could come back and demand it for my research.

"I think it's the general standards they are concerned with — they want standards that won't have an adverse impact on them."

Nurses can provide balance

Elaine Larson, RN, PhD, FAAN, CIC, professor of pharmaceutical and therapeutic nursing and IRB chair at Columbia University Medical Center, New York, NY, says she was not at all surprised by Rothstein's findings.

"Nurses see themselves much more as patient advocates for the individual patient, whereas researchers often see themselves as generating new knowledge and maybe not so attentive to the interests of the individual patient," she says. "There may be a little bit of a perspective or cultural difference."

However, she says that when taken to extremes, a patient advocacy role can have a downside, causing nurses to act as gatekeepers who view researchers as the enemy. On the other hand, researchers may demonstrate an opposite extreme, showing less concern about individual subject welfare.

"In the IRB, we do sometimes get [proposals] like, 'Let's do a muscle biopsy in a healthy child,'" she says. "We would say no to that, because it's somewhat painful, it's not free of risk and there's no individual benefit, nor is there a clear rationale for what it adds to generalizable knowledge."

She says both extremes — too much protectiveness, or too little — are harmful.

"The one extreme is 'Nobody's going to touch my patient to do anything unless it's therapeutically and directly beneficial.' That's a problem, because how in the world are we supposed to know what's beneficial unless we try it in some systematic way? And that requires research," Larson says.

"On the other extreme, from the researcher's end, is the idea that our main goal is to increase knowledge, and if it's not pleasant for a few people, it's worth it. That's not good either.

"I think there needs to be a better team approach to research, where the clinicians and researchers understand that, together, they're trying to make it better for patients."

Larson notes that for most of her career, she has been the only RN on her IRB. But she says nurses aren't the only professional group that advance the patient advocacy end of the spectrum, pointing to social scientists and public health workers as examples.

"So I have a feeling that it's probably not nurses, it's probably people who are primarily in the social sciences," she says. "Nursing is sort of standing between two worlds — certainly the biologic sciences, but we're also interested in some of the sociological and cultural factors that have to do with illness."

She agrees with Rothstein that it would be beneficial to add more nurses to provide that essential counterbalance to the researcher perspective — even to the extent of not focusing so much on adding unaffiliated members.

"We have wonderful lay members, but they really can't say a lot," Larson says. "What they do say is to tell us that the consent form isn't understandable. That's a very good perspective. But honestly, there needs to be members who are of the patient advocacy end of the spectrum who also understand the biology of what's going on."

Both Rothstein and Larson say having one nurse on an IRB is not enough to ensure a robust discussion about ethical issues.

"When they're on their own, it takes a lot of bravery to say something in an IRB with all these very strong researchers and mature people who have a lot of clout in the organization," Larson says.

Rothstein advises limiting the number of MDs on an IRB and trying to recruit more non-MDs. "You have to think in those terms," he says. ■

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IRB administrator revises IC policies & procedures

Interests of reading and hearing-impaired included

Very few informed consent policies are extensive enough to convince one IRB director that the protections are extended to everyone who might be asked to participate in a study.

"We do have an informed consent policy, but I knew we needed to address formally the process that went along with informed consent for those people who could not undergo the normal or usual consent process," says **Jana L. Lacera**, RN, MSA, human protections administrator and director of the IRB and Bio-Ethics for Community Healthcare System in Munster, IN.

"How do you address people who don't speak English or don't speak it well?" Lacera says. "We do have a language line we could use, but it's never been written down anywhere."

Lacera had created all of the IRB office's policies and procedures from the ground up a few years ago when she was offered a job to be the IRB office's first director. Before she had completed the task, the institution was audited by the FDA during a routine visit, she says.

"Your hands sweat when you get that call on a Monday morning, and it was just a routine visit, and we came out very, very well," Lacera says. "We had only one recommendation because I hadn't completed our medical device policies yet."

Within two weeks, Lacera had finished those policies, as well, and resubmitted the policies to the FDA.

Now, she has returned to the informed consent policies to improve those.

"Our policies did nothing to address the people who can't read, and we have a low rate of literacy in our country," Lacera says.

Lacera also identified the hearing and visually impaired as potential research participants who would have trouble with the standard consent process.

Having spent years as a nurse and director of an intensive coronary care unit, Lacera often encountered patients with these communication issues.

"So, often we'd see patients who had procedures explained to them and their families, but they really didn't understand," Lacera says. "I think it's very important in protecting the rights of the patients that they understand what we're telling them."

"When I started working for the IRB, I found the informed consent forms daunting, even though I'm a medical professional," Lacera says. "So I thought, 'How does the average person get through the 25-page consent form?'"

Although the IRB and investigators have strived to have these forms written to an eighth grade reading level, Lacera is unconvinced that they've succeeded in this goal.

"I go over every single consent form written for our IRB, and I can tell you they are not written to an eighth-grade reading level," she says.

The problem is that many people who provide input to the informed consent forms are professionals who do not work directly with participants, and they each have their own professional language and terminology that ends up in the document, she says.

"I understand that we health care professionals speak a different language, and lawyers need to understand they speak a different language, and not all of our subjects understand those languages," Lacera says.

Lacera decided to fix these problems through a revision of the policies and procedures concerning informed consent. Here's how she did it:

- **Look at what other IRBs have done:** "I love to look at other people's Web sites, and there are some wonderful policies and procedures out there," Lacera says.

Most institutions include their forms and rules online, sharing their information with others in the human subject protection field.

But despite a thorough look at IRB Web sites from coast to coast, Lacera was unable to find any policies and procedures that covered all of her concerns.

"Nobody addresses informed consent further than non-English language patients," she says. "I only saw one policy and procedure that talked about low literacy, and it alluded to that within the process of oral presentation."

- **Address the major barriers in written policy:** Lacera selected these three areas to revise in the informed consent policies and procedures:

- English as a second language participants: "If the patient or subject doesn't speak English, or doesn't speak English well, then the investigator will have to provide an interpreter, and the interpreter cannot be a family member or friend," Lacera says.

It's well documented that using informal interpreters can lead to communication problems since most people are not fluent in translating medical language, Lacera explains.

"So, the policies will require a certified interpreter," she adds. "We have a large Spanish-speaking population and a rather large Indian population."

The hospital already contracts with a telephone interpreting service, and this can be used by researchers, as well, Lacera notes.

- Deaf participants: These potential participants pose a unique challenge, so Lacera proposes placing them in a separate category. "We have a sign language interpreter we can contract with," Lacera says.

- Low literacy/blind participants: Participants with either of these challenges are addressed in one category because they both would have problem with a written informed consent, Lacera says.

"What we're going to have to do is look into training witnesses so they can be objective observers of the informed consent process," Lacera explains. "And when they co-sign the consent, they are actually witnessing that the subject understood the consent, including the risks and benefits of what they've been told."

The trained witness would need to be someone who is not involved in clinical research, but could be a volunteer from among the institution's staff, she notes.

"I would like to be able to train several people within the system on what is a good informed consent, so they could be trained witnesses, trained observers," Lacera says.

The training would be similar to what IRB members experience, including a video about human subjects protection, she adds.

• **Seek input from others:** "Right now, I'm finishing the policy on overcoming barriers to informed consent, and then I'll take it to the clinical research staff for their input," Lacera says.

She'll ask for answers to these questions:

- Is this something that's doable to the investigator?
- Does this make the process too cumbersome?

"I'll listen to their input, see what they think, and make revisions before presenting it to the IRB," she says. "By that time, hopefully, we'll have corresponding clinical research suggestions in place also."

The informed consent revisions should take about four months before they are ready to be included on the IRB's Web site, Lacera says. ■

"Minimal risk" poses ethical issues to IRB, investigators

Expert discusses interpretation problems

The federal regulations leave the job of interpreting "minimal risk" up to IRBs, which can lead to challenges for ethics boards and investigators.

"There is language in the regulations that everyone knows, and they're widely agreed upon as an appropriate standard, saying that minimal risk is the risk experienced by a normal child in everyday life," says **John Lantos**, MD, a professor at the University of Chicago, division of biological sciences in the department of medicine in Chicago, IL. Lantos is a former IRB associate chair, and he published a paper about minimal risk in the *American Journal of Bioethics* earlier this year.

"But no one knows how to operationalize that definition when they're trying to use it as a criteria for acceptability for a particular protocol," Lantos says. "What happens is that both individuals and IRBs come up with their own interpretation of this, and their interpretations seem to differ quite wildly from one IRB to another."

For example, IRB members often have difficulty evaluating the risks of surveys, Lantos says.

"How stressful is it to ask people questions about sex or drugs or school performance, and the answer is that no one really knows," Lantos says. "The follow-up question is, 'How do those risks compare to risks of everyday life?' and it becomes a fairly subjective standard."

Investigators involved in multi-center protocols, which have to go through many different IRB protocol reviews, experience the arbitrariness of IRB decisions first-hand, Lantos says.

"Some will approve the protocol, some will reject it, and some will ask for specific changes," Lantos says. "There's no real recourse or appeals process when that happens."

Even medical procedures can have multiple layers of risk, depending on how deeply an IRB chooses to delve into the issue, he notes.

"Most IRBs would consider a needlestick to be of minimal risk," Lantos says. "But the question of what is going to be done with the blood is more complicated."

Would the IRB consider it greater than minimal risk if the investigator planned to test some-

one for certain genes that are known to predispose a person to diabetes, for instance?

"Some people say that's minimal risk, but others say, 'No, that's a completely unforeseen potential harm that puts it above minimal risk,'" Lantos explains.

The solution is not to have regulators or a committee come up with more precise standards because any regulation has to be written in such a way that you can apply it to a wide range of studies, from an interventional cancer protocol to a survey to an epidemiological study, Lantos says.

"So, there's no way the regulation will precisely cover all of those in a way that doesn't lead to variation," he adds. "But the question is whether people see the variation as a problem."

To Lantos, this variation is a problem, and the sensible solution would be to have an appeals process so that investigators who disagree with an IRB's decision can appeal it to a separate body.

"So if one IRB says, 'Oh this questionnaire clearly has greater than minimal risk,' and another one says, 'No, it does not,' then an appeals body could resolve the issue," Lantos says.

"Right now, the decisions are sealed and confidential, and no one knows the basis for their decision-making, and no one can appeal the decision," Lantos says.

"It seems like it would be a much better system if investigators could appeal it to a higher court and have them publish a written decision," he adds. "You may not like the decision, but at least they can explain why they reached it."

Any oversight body would have to be based outside the institution that represents the IRB and researchers, and depending on funding, it could be created to work like a federal appeals court or a district court, Lantos suggests.

"You can imagine one housed in the Office for Human Research Protection which is comprised of experts in research ethics and health law," he says.

This idea would no doubt have its detractors, he says.

"One of the things that makes this proposal so radical is that right now IRB deliberations are treated as confidential," Lantos says.

Confidentiality does not serve human subjects protection, he says.

"The only reason to keep them confidential is to protect investigators and institutions," Lantos says.

Besides serving on an IRB, Lantos has experienced the IRB from the other side of the aisle, and it's these experiences that have led him to his proposal of an appeals process.

For example, Lantos was working with a community theater group that performed original musicals in high schools, focusing on topics such as teen pregnancy, drug use, and gang violence.

"They were taking the show around to schools and performing it, and the actors would stay afterward and have discussions with the kids about how they make decisions about joining a gang and those sorts of social issues," Lantos explains.

"In one show, one of the kids brings his policeman dad's gun to school, and someone else ends up with the gun and a kid gets shot," Lantos says. "It was a dramatic scene, and a researcher wanted to evaluate it."

The researcher took the proposal to an IRB, which decided that the scene might traumatize some kids, so it would be above minimal risk, and the IRB rejected the protocol, he says.

"I pointed out that the kids already are watching the show, and the study was just about the researchers evaluating it," Lantos explains. "You could argue whether or not this was below or above minimal risk, but once the IRB said 'No,' there was nothing else to do."

The play continued to be performed with the violent and dramatic scene, but it couldn't be studied, he adds.

In another example, Lantos was involved in a project with community health workers in a Chicago neighborhood containing Mexican immigrants.

"The health workers were lay health workers — not doctors and nurses — and the project was to see whether they could go into people's homes and do assessments of asthma risk factors, working with parents of children with asthma to reduce home triggers, such as dust, pets, carpets, etc.," Lantos explains.

"Most of the people we wanted to study spoke only Spanish, and the community health workers spoke Spanish," he adds. "So we developed an informed consent form that spoke in a simple and colloquial language, explaining what the health workers would do, and we took that to the IRB."

The IRB said the informed consent form was inadequate because it didn't have the standard boilerplate language, and they required investigators to revise it according to their standards and then use a certified translator to translate it into Spanish, Lantos says.

"This meant we basically came up with a form that was unintelligible to the people we wanted to study because it was full of legal jargon and things

about the university not providing emergency care if they were harmed in the study that were inapplicable to this particular project," Lantos says.

Investigators used the revised form, and the community health workers told them that when they presented it to the participants, they basically told them that the form was meaningless, and instead, explained what the study was about, Lantos recalls.

"If there had been an appeals process, we would have gone through it, and who knows what they would have said," Lantos says.

The problem is that while IRBs are meant to be an independent board of peers, many institutions now have so many rules and legal considerations that the IRB's independent discretion has been eroded, Lantos says.

Institutions fear that if an IRB makes a mistake and violates federal rules, then the government might shut down the institution's research program, and so they interpret the rules conservatively, he says.

"But if all you're doing is deciding whether or not something meets the rules, then all you need is one lawyer or bureaucrat to evaluate it — the way someone does a contract for employment — and you don't need an ethics committee," Lantos adds. ■

Institution establishes best practices for IRB, research

Policies are continually revised and improved

For many IRB offices, it's difficult to find time to handle the daily ethics review work, and so revising policies and implementing new policies can be a difficult challenge.

However, one Maryland institution has made best practices and policy revisions and improvements a major focus and priority, and the improvements have resulted in positive feedback from investigators and rapid responses to industry changes.

"In 2004, there was an institutional awareness that we needed to put resources into creating a more viable human research protection program," says **Debarati Dasgupta**, MS, CIP, an IRB administrator with Adventist HealthCare Inc. of Rockville, MD. The IRB office handles work from two IRBs, both located at acute care hospitals in Maryland.

"Institutional administrators looked at the current system and said, 'There must be a way to bring our processes and procedures together to make sure we're running on one set of wheels,'" Dasgupta says.

Administrators formed a committee consisting of current IRB chairs, legal counsel, a regulatory counselor, IRB staff members, and administrators from various entities that conduct research. The committee helped to create policies and procedures for an IRB handbook and templates, including these: an informed consent form template, an IRB application form, a consent form template for the use of humanitarian use devices, and protocol and informed consent checklists, Dasgupta says.

"Now we've rolled out the first three versions of some of our policies and procedures, and we revise these on an ongoing basis, as the regulatory environment changes," Dasgupta says.

Other changes include the implementation of an IRB customer service and policies feedback survey, the continued operation of an IRB oversight committee that meets quarterly, and revised forms, such as those for reporting adverse events and unanticipated problems.

The result has been a very responsive human subjects protection program that receives feedback from investigators and others and immediately implements their suggestions, Dasgupta says.

"What we've tried to do is reach out to the research community and make sure we hear their gripes, as well as their praise of what we do well," Dasgupta says. "It's a win-win situation."

Here are details about how the IRB office and institution have made these best practice improvements:

1. Improve quality through survey feedback.

"We stress customer service," Dasgupta says. "There are units at Adventist Healthcare that use a customer service survey that is built on a Web-based platform, and we were able to build a Web link that holds a customer service survey."

Called the "IRB Customer Service and Policies Feedback Survey," it has two parts, including a rating of customer service and comments on the IRB protocol review process, she says.

"They receive a short, one-page memo with a link to the survey, and it's addressed to the principal investigator and research coordinator," Dasgupta says. "They are requested to distribute it to all research team members so we can capture their input."

The survey asks investigators and their clinical trial staff to answer various questions related to the IRB office's service during the protocol review process. The survey is distributed whenever a new investigator receives an initial IRB decision on his

or her protocol application with the IRB, and so it is an ongoing survey in which feedback is tabulated on a regular basis, she explains.

The survey allows users to rate statements from strongly agree to strongly disagree and provide input on the strengths and areas of improvement for customer service, the protocol review process, and policies and procedures. Here are some sample items from the survey:

- IRB staff members consistently conduct themselves in a professional manner;
- IRB staff members are able to address my needs when a request is made in their area of expertise;
- IRB staff members consistently follow up on my inquiries;
- IRB protocol reviews are completed in a timely manner;
- Required changes to research protocol materials are clearly conveyed;
- Conditions for approval are conveyed in a timely manner.

The survey was first sent out in February 2007, and the feedback, so far, has been very helpful, Dasgupta says.

Many of the comments have helped provide continual quality checks of the IRB office staff, including the positive feedback that one executive assistant in the IRB office had been very helpful in getting a researcher's application processed in a timely manner and a comment that the IRB staff has sound knowledge of the regulations, Dasgupta recalls.

"One user said the application and protocol template was very well laid out, and the assistance was skilled and efficient," she adds.

In other cases, the feedback has drawn attention to deficits in the program, and these will be addressed, Dasgupta says.

For instance, one respondent asked for additional education on using the IRB forms. After receiving this feedback, the office will be offering customized educational sessions for clinical trial staff.

Another survey respondent requested the conditional approval letter to be sent out in a more timely fashion, and the office is working on providing a quicker turn-around time, Dasgupta notes.

Comments have ranged from the formatting of IRB forms to questions on the use of forms and templates, she says.

2. Form an IRB oversight committee.

The IRB oversight committee consists of the same professionals who were on the original committee that wrote the IRB handbook and developed templates, Dasgupta says.

"We meet four times a year to discuss system-wide issues of human research protection across the Adventist Healthcare System," she says. "At these meetings we review revised policies, and it's my responsibility, along with the IRB staff, to take a look at our current policies and make sure we're in compliance."

Here's an example of topics discussed in the past:

- The director of the institution's Center on Health Disparities spoke about the resources available and in development to help with the issue of the recruitment and enrollment of non-English speaking research participants, Dasgupta says.

"We've been working with the center to operationalize a policy in terms of making sure we are reaching out to community members and including them in our research program," she says.

- The revisions to policies and procedures are reviewed.

"We recently voted to approve a revised policy regarding the IRB appeals process," Dasgupta says. "The committee reviewed two revised policies and five revised forms from the IRB handbook and developed a new unanticipated problems reporting form."

CE/CME Objectives

The CE/CME objectives for *IRB Advisor* are to help physicians and nurses be able to:

- **establish** clinical trial programs using accepted ethical principles for human subject protection;
- **apply** the mandated regulatory safeguards for patient recruitment, follow-up and reporting of findings for human subject research;
- **comply** with the necessary educational requirements regarding informed consent and human subject research.

COMING IN FUTURE MONTHS

- Preventive misconception: Protecting subjects in prevention trials
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- Here's a case study on an IRB asking for more than a sponsor can provide
- Some institutions have scientific review first — here's how it works

• The committee has discussed the need to revisit the areas of conflict of interest and financial disclosure and the plan to address the most favorable IRB structure for the system, Dasgupta notes.

These meetings typically are very productive, requiring considerable work prior to the meeting and afterwards as a follow-up, she adds.

• Also, the IRB oversight committee is the appropriate forum to address system-wide issues and issues that the IRB committee may not have the time to handle, Dasgupta says.

For example, the IRB oversight committee has, in the past, discussed a study in which a research team was interested in participating. The committee reviewed study factors such as study design, the risks and anticipated benefits to subjects to determine if the institution's involvement is acceptable, she says.

3. Create new templates and revise existing ones.

Once forms are distributed, feedback is received from research staff, and that feedback is taken into consideration when revisions are made, she adds.

"At this stage, we anticipate revising forms and policies on a quarterly basis, Dasgupta notes.

"Revisions are based on the feedback from users and new guidance and regulations out in the field to make sure we're in constant compliance."

Revisions also are discussed by the IRB oversight committee, she notes.

CE/CME *questions*

5. *True or False:* People traumatized by a natural disaster will invariably become less vulnerable over time, as they get over the initial impact of the disaster.

6.Which of these groups of IRB members rated ethical issues as most important to them personally?
A. Physicians
B. Nurses
C. Risk managers
D. Unaffiliated member

7.According to an IRB administrator who has researched informed consent policies, which special population among research participants often are not addressed in IRB policies and procedures?
A. Non-English speaking participants
B. Deaf, blind, or low-literacy participants
C. Children, prisoners, and disabled participants
D. All of the above

8.Which of the following would be good question to include in a survey to evaluate the IRB review process?
A. Do IRB staff members consistently conduct themselves in a professional manner
B. Are IRB protocol reviews completed in a timely manner
C. Are required changes to research protocol materials clearly conveyed
D. All of the above

Answers: 5. (False); 6. (b); 7. (b); 8. (d)

The adverse event reporting policy and form, and the unanticipated problems form, were among the more challenging ones addressed, Dasgupta says.

"Our biggest challenge has been on handling non-local serious adverse events (SAEs) and determining where our local IRB responsibility rests," she says.

"Our IRB needs to be notified of risk study-wide, but how do we handle the huge load of external SAEs that are coming through our door?" Dasgupta says. "How do we process efficiently and capture the data presented to us and put it into perspective?" ■