IRB ADVISOR

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Report: Give investigators more authority to approve some protocols

Says certain protocols should be exempt from IRB approval

The American Association of University Professors (AAUP) released a report taking IRBs to task over what they call "inappropriate, indeed absurd, alterations in research protocols" and overly stringent guidelines for study submission and approval.

The AAUP calls for more researcher autonomy for deciding whether a federally funded study needs IRB review, rather than relying on IRB members who "have no special competence in assessing research projects in the wide range of disciplines they are called on to assess, whose approval is required for an only minimally restricted range of research projects … who are only minimally restricted in the demands they may make on the researchers, and whose judgments about whether to permit the research to be carried out at all are, in most institutions, final."[1]

The report comes in response to the U.S. Department of Health and Human Services' (HHS) 2011 advance notice of proposed rulemaking (ANPRM) for potential changes to the Common Rule.

The AAUP analyzed 1,100 responses sent to HHS and found behavioral, social, and humanities researchers have what the report calls "horror stories" and many complaints about overly cumbersome and complicated approval requirements and too-short lists of exempt study types.

The report, titled *Regulation of Research on Human Subjects: Academic Freedom and the Institutional Review Board*, proposes the following:

"Research on autonomous adults should be exempt from IRB approval (straightforwardly exempt, with no provisos and no requirement of IRB approval of the exemption) if its methodology either:

(a) imposes no more than minimal risk of harm on its subjects, or

(b) consists entirely in speech or writing, freely engaged in, between subject and researcher."[1]

Under HHS regulations published in 1995, such studies are exempt from review under 45 CFR 46.101(b)(1)-(6), unless the subjects' responses could lead to subject identification, and if disclosure of the subjects' responses outside of research could be personally damaging or bring civil or criminal liability. It is left to IRBs to determine whether such studies are exempt.

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Editorial Questions

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The Office for Protection from Research Risks (OPRR) "advises that investigators should not have the authority to make an independent determination that research involving human subjects is exempt and should be cautioned to check with the IRB or other designated authorities."[2]

The AAUP produced two previous reports on the issue, in 1981 and 1996, in what one study author says was a response to "widespread unhappiness" researchers felt with IRB approval regulations. After HHS's ANPRM in 2011, the AAUP decided to update its report in response. "It was timed as a response to the advance notice, even though the report itself came well after deadline," says **Zachary Schrag**, PhD, co-author of the AAUP report and professor of history at George Mason University in Fairfax, VA.

While critical of IRBs, the report is not an indictment of the system. "Many people report favorable experiences with it. Many researchers have thanked IRBs for helping them think through the moral issues raised by their work, and many present and former IRB members report that their IRB contributed substantially to developing the research projects they assessed and to protecting the research subjects," the report authors note.[1]

Schrag also points out that the report is mainly from a university research perspective rather than a hospital one, and that it does not call for the abolition of the IRB system for medical research. The recommendations, he says, apply only to "studies where adults are talking to adults — when the conversations are restricted, the challenge to academic freedom is the most obvious."

While **Mark Schreiner**, MD, chairman of the committee for the protection of human subjects at Children's Hospital of Philadelphia (CHOP), agrees that some IRBs do overstep their bounds, he says that approval issues do not lie in the regulations but in IRBs themselves. "Inexperienced IRBs are afraid to do the wrong thing, and it results in conservatism," Schreiner explains. For example, an IRB may require investigators to use extra consent forms just to be on the safe side — which is a waste of time for everyone, Schreiner says.

"If they [IRBs] are overstepping the bounds of their authority and deciding a study needs to go to IRB for review, I can see the problem there," Schreiner says.

By not "checking the box" to apply Federal-

Wide Assurance to non-federally funded research, IRBs have greater flexibility and oversight. "There has been an increasing trend in unchecking the box, and a majority of IRBs are taking advantage of increased flexibility," Schreiner says. "I would propose that everyone consider unchecking the box and not applying the same stringent standard to all research. By not checking the box, IRBs have lots of ways to increase flexibility."

"Instead of relaxing the regulations, let's educate the IRBs to use their flexibility," he continues. "The AAUP presents the issues as problems with regulations, but over and over again they're problems with the IRBs."

For the AAUP, the issue of protocol approval doesn't lie entirely with efficiency, but with academic freedom. "The AAUP is not interested in efficiency so much as freedom," Schrag says. "It's not a term that gets included so much in human subjects protection. Freedom is not one of the big issues and can often be forgotten as people discuss this issue. The unique or special function in this debate is to assert the value of freedom."

For now, Schrag says, the big question among administrators and researchers is what the federal regulators will do. "Since the close of the comment period in October 2011, we have only the vaguest rumors on the progress of that reform effort," he says.

The full AAUP report can be found at http://www.aaup.org/file/IRB-Final-Report.pdf.

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Templates could build better informed consent

Interactive tool is praised by users

Years of improvements to the informed consent process and many hours of developing tools and templates to assist IRBs and investigators in fine tuning informed consent documents have helped pave the way for Consent Builder.

Created by IRB experts, Consent Builder is the next generation of template documents, says **Becky Armstrong,** DVM, PhD, director of the office for protection of research subjects, University of California at Berkeley.

"The informed consent process is the point of contact between researchers and their subjects, and it's where IRBs can have a fair amount of impact," Armstrong says.

Launched a year ago, the Consent Builder application has been popular among researchers, especially those starting out, she notes.

"I received one comment from a graduate student who said, 'Thank you — I would never have been able to write a consent form without it!'" Armstrong says.

The Consent Builder application is available to all investigators who work with UC Berkeley through a password-protected website. The software is not being copyrighted, so other institutions and IRBs can access it at a public site at http://ucb-rac.github.com/consent-builder/, she adds.

Building a simpler IC process

The IRB made a goal of developing better guidance documents and templates for investigators. About nine years ago, the IRB provided minimal information on its website about informed consent, including instructions to principal investigators (PIs) and a checklist, Armstrong says.

"We started by putting together general informed consent guidance and built from there," says **Louise Tipton,** EdM, CIP, IRB administrator for the office for protection of human subjects at UC Berkeley.

Tipton led teams to develop guidance and templates for biomedical and social-behavioral studies. The guidance came to include sample consent forms for various types of research.

"We want to have a user-friendly website, and we try to provide all the materials researchers might need to answer their questions," Armstrong says.

These efforts to promote a better informed consent process eventually led to developing the Consent Builder online tool.

Consent Builder is a user-friendly, interactive application that aims to improve the consistency, completeness, and readability of human research consent forms. The researcher moves through a series of screens, answering questions about the

study and completing text boxes as instructed. Answers to questions help direct the next questions, skipping irrelevant ones. The researcher can then download the created consent form in Word. The Word document includes IRB standard language and formatting, and can be edited further if needed before submission.

UC Berkeley adapted the Consent Builder application from one that had been created a decade earlier at UC Irvine, Armstrong notes.

"UC Irvine had developed it in the early 2000s; then, as part of the National Institute of Health's funding program to encourage human research protection programs to develop materials, share things, collaborate, and make the whole IRB world better, UC Riverside got Consent Builder from Irvine, and we got it from UC Riverside," she explains.

After a long hiatus where the project was on backburner status, Tipton was assigned to work as the content source for Consent Builder, coordinating with two expert information technology (IT) programmers in the department.

"We had just gone through a major transition of moving our whole application to an electronic system ... so this was a good time to update the consent tools as well as get some staff resources for the project," Tipton explains.

Initially, everyone hoped they could make minor adjustments to the application and then roll it out.

"It turned out there was quite a bit of reworking that had to take place on both sides," Tipton notes.

"We had been working on it for five months when the programmers said, 'The software is pretty archaic. We can keep working around that, but if you want this to be robust and flexible enough to allow for changes and adaptations in the future, then we should basically start over and rebuild it,'" she recalls.

"It made sense for the long term, so we agreed," Armstrong says.

Keeping it "clean and simple"

On the content side, one important element was to have the investigator walk through the application and complete the fields; the program would adapt these answers, add standard language, and produce an informed consent document that could be further edited and adapted as needed, Tipton says.

The templates tended to be very long, so the goal for Consent Builder was to achieve simplicity and brevity as much as possible, she adds.

"The Consent Builder application goal was to have it clean and simple: You answer a series of questions after choosing biomed or social-behavioral or both for your type of research," Tipton says. "Consent Builder was a very lengthy project; it went through a lot of adjustments and restructuring to try and reach that goal of simplicity."

Even so, as Armstrong points out, the program has its limitations.

"It follows the flow of how we have written our templates," she explains.

The informed consent templates and sample forms were created five years ago, and although they have been updated and improved along the way, they may be due for further refinement, Tipton says.

"We've tried to work on the language to make it simpler and more toward our goal of having a consent form that is at an eighth-grade reading level," Armstrong says. "But we have to be realistic and not try to redo the entire system in the course of creating this one tool; so it's similar to the templates we have, but with improvements in terms of readability and clarity."

"In an ideal world with lots of staff time and resources, we'd update our templates to be more like Consent Builder," Armstrong says.

For now, though, Consent Builder seems to be providing a valuable addition to the researcher's toolkit, showing the way for future improvements to the consent process for investigators and subjects alike, Tipton says. ■

Consent Builder relies on plain language templates

Key is use of sections, clear statements

The University of California at Berkeley's Consent Builder application relies on the simplified language and template structure previously developed by the institution's IRB office.

"We had to do a complete overhaul of informed consent guidelines and create more specific tools and resources," says **Louise Tipton**, EdM, CIP, IRB administrator in the office for the protection of human subjects.

"We've had to emphasize that consent was

not just a form," she adds. "It's a process of putting all of these elements together to have a completely informed individual who makes this decision."

A standard sample consent form created by UC Berkeley's IRB incorporates the elements of informed consent required by federal regulations on human research (45 CFR 46.116) and includes these sections:

- introduction;
- purpose;
- procedures;
- benefits;
- risks/discomforts;
- alternatives (if appropriate);
- confidentiality;
- compensation/payment;
- rights of the subject;
- questions;
- signed consent.

The language in each section is kept simple and direct. Under "risks/discomforts" for instance, the information is presented in bullet points. An interview consent might say, "Some of the research questions may make you uncomfortable or upset. You are free to decline to answer any questions you don't wish to, or to stop the interview at any time."

Under the procedures section, a bullet point might explain a DNA testing procedure this way: "You will be asked for a cheek swab to sample cells for DNA testing. This involves briefly wiping the inside of your cheek with a cotton swab."

The application resulted from several years of work at UC Berkeley's IRB. The organization inherited a program called Consent Writer from a sister institution and adapted it by incorporating informed consent guidelines, biomedical and social-behavioral consent templates and sample forms, and using standard and recommended language for consent documents.

"Improving the overall informed consent process was a big milestone we needed to meet," Tipton says.

Custom-built consent forms

The UC Berkeley Consent Builder features screens that ask the researcher a series of questions. The answers are used to generate an informed consent document that reads as clearly and concisely as the informed consent template in hard copy format.

One screen about the study purpose asks these questions:

- What is the purpose of this research?
- Briefly describe what the study is designed to discover or establish.

Another screen addresses inclusion criteria. It asks, "Why is the individual being asked to take part in this study?"

In other parts of the application, a researcher is asked to describe benefits of the study. If the researcher has not checked the "direct benefit" box in a previous screen, this screen will show standard language for a study that has no individual benefit to the subject, but does anticipate general benefits, such as benefits to others, society, and/or scientific knowledge: "No direct benefit to you is expected from participating in this study. However, we hope that the information gained from the study will help…" Researchers can add to and edit those words before clicking on "save and continue."

The application also allows the user to go back and make changes to any screen along the way. The last screen of the Consent Builder asks if the user would like to generate a Word-format consent form now. This form will take all the answers that have been entered and present them as statements, along with appropriate standard language, in the generated form. If the answer is "yes," a consent form in Word is created. The researcher then can save this form and do further editing as needed before submitting it as part of a protocol for IRB review.

In the year since Consent Builder was implemented, it has worked well, Tipton notes.

"In that time, there have been only a few occasions when someone has had problems accessing it, and the IT team fixed it right away," she says. "And feedback to our staff analysts in the office and at our educational outreach sessions has been very positive. The result was worth the time and care we took to test it out and to make sure both the technical and content aspects were fine."

However, the Consent Builder application will not be used with studies involving minors because of the more extensive requirement differences, Tipton notes.

"So if people are doing research with children, we refer them to our specific guidelines and sample forms for such studies," she explains.

The Consent Builder application will be improved as users provide more feedback, she adds.

"There are still some improvements that need to be made, but it's been a healthy system so far and has been helpful to our research community," Tipton says. "We just hope that continues to be true." ■

Provide brief, effective performance reviews

Self-evaluations included in process

Sometimes an IRB director will notice that board members lack interest in evaluation processes. Any attempt to assess how each member is doing might be shuffled to the back burner of the schedules of very busy people. So what can an IRB do to improve its IRB member evaluation process and obtain board buy-in?

The answer, one expert says, is to design a very short but effective review process.

"Before this program was implemented, we had a program where IRB chairs evaluated the members," says **Virginia Rhodes**, RN, MSN, human research protection program coordinator at the Durham VA Medical Center of Durham, NC.

"People didn't take it seriously," she adds. "When we started this program and had peer reviews, interest skyrocketed; people want to be held accountable and do a good job."

The Durham VA Medical Center's new IRB member evaluation program provides a brief but thorough review of all IRB members. It has four parts: self-evaluation, peer evaluation, IRB chair evaluation, and research office staff evaluation.

"We didn't want to create a process that creates more work for people who already are busy," Rhodes says. "But we want a process that shows how the IRB has functioned as a group."

Here's how the organization created an effective and popular evaluation program:

• **Brainstorm to identify the best ideas.** Rhodes met with the IRB chair to discuss the evaluation process and to point out that the existing process was insufficient.

"We were talking about the evaluation process, and he said, 'It's kind of a chore; people don't get much out of it,'" Rhodes recalls. "So we brainstormed about how to make it better, and we thought by involving members we could have more positive feedback on the whole process."

• **Create a survey.** "We didn't want the survey to be overly burdensome," Rhodes says.

The evaluations ask for ratings from 1 (poor) to 5 (excellent) on each question. For peer evaluations, IRB members rate each of their peers on two questions. And each member rates him- or herself on the same two questions, which are as follows:

- How would you rate the quality of your [this member's] protocol reviews?
- How would you rate the quality of your [this member's] contributions to IRB discussions?

For the IRB chair, there are three questions, as follows:

- How would you rate the quality of this member's protocol reviews?
- How would you rate the quality of this member's contributions to IRB discussions?
- List briefly any contributions this member made above and beyond protocol review and discussion, especially those that contributed to improving the IRB's policies and procedures.

The IRB staff were asked to complete these questions:

- Out of 12 meetings (regular and urgent) held by the Durham VAMC IRB between April 30, 2011, and May 1, 2012, how many meetings did this member attend?
- How proactive is this member in identifying concerns with IRB review packets/individual submissions?
- How quickly did this member answer PI [principal investigator] requests?

The two IRB co-chairs evaluate each other and do self-evaluations, as well. The administrative staff also evaluates the chairs, Rhodes says.

• **Look at individual IRB members' statistics.** The IRB member evaluations by the IRB administrative staff provide useful data, which can be used to provide feedback to individual members, Rhodes notes.

"Five members of the office rate all reviewers," she says. "The administrative staff gives an assessment of each member to the chair, and the chair can bring that up with the member at a one-on-one meeting if it's an issue."

Their ratings for the two questions about how proactive the member is in identifying

concerns and how quickly the member answers PI requests are based on a number of factors, including these:

- Were there any issues with the packets they received, and how quickly do they look at the packets and ask the staff about any identified problems?
- How quickly do they respond to administrative requests?
- Do they get responses back quickly or not?
- Do they respond to PI requests in a timely manner?

"Once a review is done, investigators can send their questions directly to the IRB reviewer," Rhodes explains. "PIs do not know initially who did the review, but if they have any questions about recommendations after it's done, they can direct these questions to the member who did the review."

• **Use evaluation results to improve performance.** The IRB chair meets one-on-one with members to discuss their evaluations. It gives the chair a good sense of each person's strengths and weaknesses and helps to identify items to work on, Rhodes says.

"If the member's evaluation is great then that member can share what he or she is doing with other members, and we'll talk about it at meetings," she says.

This could be part of the meetings' continuing education focus in which members share new things they've learned, she adds.

• **Address IRB review issues that arise.** "One of the issues that came up involved timeliness in reviews and getting information back to the office," Rhodes says. "The administrative staff crunched numbers, looking at how many meetings IRB members attended, how quickly they responded to the principal investigator."

The data revealed some concrete examples of areas that could be improved.

"Our chairs could say to an IRB member, 'Is there something we could do to help you be more proactive? Can we get this material to you in a way that is easier for you to handle?' Rhodes says. "We could deal with this on a case-by-case basis."

Data collected through the evaluations has made it easier to identify problems.

"With this process we can pinpoint where there might be a problem, and we can address the problem," Rhodes says. "Before, it was easy for people to complain that someone was slow in responding, but unless you have data showing how far off the mark they are, you can't do anything about it."

• **Handle remaining challenges.** "The biggest challenge is finding time for the IRB chair and members to spend 10 minutes or 20 minutes talking about the evaluations," Rhodes notes. "That's the hardest part."

They decided the solution would be to set up these discussion times right before and after IRB meetings, she says.

"That seems to have worked well, and we'll do that again for the next cycle," Rhodes adds.

"The evaluation change has been a really positive experience for our members, chairs and even the office staff," Rhodes says. "The take-home message is the accountability: You're accountable to your peers, your chair, to your office; the evaluation says, 'This is serious; this is important, and I want to contribute to the group, and I also want to do great reviews for our researchers.'" ■

Program helps "RePAIR" noncompliance issues

Remediation instead of punishment

A new research ethics program seeks to repair problems when investigators misbehave or are in noncompliance.

The RePAIRprogram.org (Restoring Professionalism & Integrity in Research) was created with a $500,000 grant from the National Institutes of Health (NIH) to train investigators who have engaged in wrongdoing or unprofessional behavior, says **James DuBois**, PhD, DSc, director of the Bander Center for Medical Business Ethics and a professor of health care ethics at Saint Louis University in MO.

"We had a year to piece together a curriculum that would address someone engaged in some sort of wrongdoing in research or chronic noncompliance," DuBois says. "These could range from data integrity to IRB issues, including people recruiting inappropriate patients into clinical trials."

RePAIR is a three-day seminar program in which participants are coached through an action plan. They attend in small groups, and

the remediation is similar to what has been available in the field of medicine for years, DuBois says.

The NIH-funded program focused on both human subjects research and animal research, he notes.

RePAIR has received national publicity recently with a January article in the journal *Nature*.

"A lot of people are spinning it as a program focused on research misconduct, but we want to provide services to a much bigger group of people, including human subject researchers whose IRBs told them they are in noncompliance," DuBois says. "We're trying to get to the root causes and address the way they think about research to address biases."

DuBois conducted a survey last year that looked at how common wrongdoing is in research. It found that 96% of institutions surveyed had investigated a case within the previous two years. The problems investigated ranged from procedural — the most common — to consent issues, oversight, conflict of interest, privacy, recruitment, and fraud problems.

"We surveyed 194 research-intensive schools in the nation, including medical schools, and we found that over the past two years nearly every institution had investigated someone formally," DuBois says.

Stress is a contributor to wrongdoing, he notes.

"If you have a stressful life, like going through a divorce or bankruptcy, you can make worse decisions," DuBois explains. "So one solution is to teach researchers stress reduction techniques."

Also, there are certain personality patterns that can lead to transgressions. For instance, some people who engage in unethical behavior have self-serving biases, which include self-centered thinking, assuming the worst, blaming others, and minimizing or mislabeling problems.

Cynicism a problem

"Some people have a strong sense of entitlement or cynicism," DuBois says. "People who habitually assume the worst or think badly of their colleagues or institutions are more likely to make bad ethical decisions, and environmental factors can play a role."

In DuBois' research, he has also observed that in the human subjects protection field, wrongdoing can be a result of rules and regulations that are fairly ambiguous.

"You see some really scandalous cases where they had IRB approval," he says. "One example is the Kennedy Krieger [Institute] case — a lead abatement study that was controversial and was IRB approved."

The Kennedy Krieger Institute is a children's health and research facility that is part of Johns Hopkins University in Baltimore. The institute conducted research about low-cost partial lead abatement procedures in public housing in Baltimore between 1993 and 1995. The goal was to prevent lead poisoning in children. Two families sued the institute, saying they were not fully informed of the risks. A court of appeals issued a ruling that compared this study to the Tuskegee syphilis study and Nazi research on prisoners, calling the experiment callous for using children as measuring tools. The court focused on informed consent and said that parents could not give consent for their children to enroll in non-therapeutic research.[1]

The point is that the way IRBs interpret minimal risk has been very inconsistent, DuBois says.

"If you ask 10 IRBs if an MRI is risky or not, you get 10 different answers," he says. "So we try to identify where investigators are on the ambiguous rules and how they can gain clarity, what processes they can follow, and who can they call to get answers to questions to ensure they are proceeding in a way that would be compliant."

The goal of RePAIR is remediation, changing behavior through confronting, educating, and monitoring professionals engaged in inappropriate behavior.

What IRBs can do

IRBs can be part of the solution if they focus on how they respond to investigators' phone calls and requests, Dubois notes.

"One challenge investigators face is when they call the IRB office for guidance, the IRB staff can advise, but they're not decision makers," DuBois says. "It's really the IRB members, and sometimes researchers hear contradictory answers, and that contributes to ambiguity."

If researchers know more about a particular

topic than the IRB members reviewing the study, they need to share their information with the IRB, he says.

It's helpful to enhance and foster communication between the IRB and researchers, he adds.

"Also, earlier intervention with researchers can be helpful," DuBois advises. "Ask yourself whether the behavior problem is due to a lack of knowledge or due to something else."

If the problem is knowledge-based, the solution could include sending the researcher to a human subjects protection course or workshop through CITI or PRIM&R, he suggests.

This strategy won't work if the investigator knows the rules but just chooses not to follow them, he adds.

"What I hear about a lot from colleagues in the field is, 'We have an investigator and this problem has been festering for three years; we've had to intervene four or five times,'" DuBois says. "That problem is unlikely to change abruptly without some sort of effective intervention."

In DuBois' recent study of 100 published cases of wrongdoing in research and medicine, he found that 81% involved repeated wrongdoing.

Research institutions should look for alternative interventions when their usual measures, such as a letter of reprimand or sending an investigator for more education, fail, DuBois says.

"When you've written the letter and reminded them of the rules and still are seeing repeat offenses, that's the scenario that the RePAIR program has in mind," he adds.

When DuBois watched a RePAIR session, he observed how investigators would arrive with a chip on their shoulders, feeling punished by having been sent to the seminar.

"Within an hour they were fully participating and left, saying, 'Thank you,'" he says.

The program is expensive to run. It includes coordinators who conduct interviews with institutional officials and two faculty members who devote a week to the program, including preparation work and follow-up calls.

The RePAIR program runs three times a year with the next session in May 2013. It costs $3,000 for the course, but through partnerships with institutions there is a 50% discount, DuBois says.

"We ask them to use us for remediation training for $1,500 a year, and we give them access to a webinar each year to deal with wrongdoing," he says.

Research institutions can show their commitment to remediation by covering part of the cost when investigators are required to participate in this type of intervention, he notes.

"It sends a message to the investigator that this is not about punishment, but investing in you as a researcher," DuBois says. "They've made a decision to not fire this person."

While it may be easier for institutions to simply fire investigators who have engaged in misconduct, this is shortsighted, he adds.

"You might have someone who is not intentionally running afoul of the rules, but still is noncompliant," he explains. "In cases that turn out tragically bad and the school deals with bad press, sometimes the actual compliance failure is unintentional and not all that egregious despite its horrible consequences."

There are a lot of different reasons why someone is not in compliance, DuBois says.

"Still this is a situation that has to change, and we're in the business of helping them change and be more effective as researchers," he adds.

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Continuity plans keep IRBs going in hard times

Keep operations up during weather disasters

While monstrous hurricanes are not a frequent occurrence, it always pays to be prepared. Hurricane Sandy was something of an anomaly, but cities and hospitals in the Northeast braced for the monster hurricane, putting plans in place to evacuate patients when needed and ways to continue operations even if the worst happened.

IRB members, too, had to be quick on their feet and find a way to continue on, even in the face of flooding and destruction. **Marjorie**

Speers, PhD, CEO of the Association for the Accreditation of Human Research Protection Programs (AAHRPP), stresses the importance of every IRB having a continuity plan in place for any unforeseen circumstance that could arise.

"In just over a decade, there have been a number of events that would interfere with an IRB's operation," Speers says, referencing 9/11, Hurricane Katrina, floods in Houston, and other major weather events. "To put Sandy in perspective, it's not the first disaster IRBs have had to deal with."

How to prepare

Speers offers tips for IRBs on forming a continuity plan and keeping things moving as smoothly as possible during an event:

• **If the IRB must briefly close, formulate a plan to keep meetings going.** "It's much easier today with the information technology and software we have available," Speers says.

When the offices at the Biomedical Research Alliance of New York (BRANY), located on Long Island, were closed in anticipation of the storm, members quickly identified other places to go: each other's homes. After some IRB members lost power at home in the aftermath of the storm, they were able to go to nearby colleagues' homes to charge phones and laptops and to access the electronic IRB databases and keep things going.

"We identified people willing to have a home office for other people in the area," says **Kimberly Irvine**, CIP, CIM, executive vice president and chief operating officer of BRANY. "We could access the database, but it was good to have people willing to let others come to their home to work."

In addition, BRANY institutes a "phone chain" to get information to colleagues. Members also update voice mail greetings to reflect the closing to anyone who might call, and send out email blasts to participants to keep them abreast.

In the days following the storm, the IRB at New York University Langone Medical Center in Manhattan held a virtual meeting for protocol review, giving priority to studies with greater than minimal risk, including therapeutic interventions and device studies. "That way, patients would continue receiving medications and follow-up calls," says **Elan Czeisler**, IRB director at NYU Langone. There was no interruption in oversight, and IRB meetings resumed, with dozens being held over the phone.

• **Ensure that database systems and protocol records are safe and secure.** "Many IRBs are moving to electronic systems. That's a real plus if the docs are stored electronically in the cloud," Speers says. "The vulnerability we had even 10 years ago is much less today with electronic records."

The NYU Langone IRB had staff members in place to assist in the evacuation of records of more than 100 research protocols from the hospital and other research affiliates. The records were moved to a secure location only accessible to investigators involved in the studies. "Those staff members were actually dedicated full time in support of that effort as they were familiar with the program itself," Czeisler says.

Keeping operations running

• **Inform the federal regulatory bodies of the situation.** "It's very important to inform OHRP [Office for Human Research Protections] and FDA [Food and Drug Administration] and let them know what is happening," Speers says. "That's important because one thing you're vulnerable to is not being able to follow the regulations. If the regulatory bodies know you can't conduct continuing review on time, they can work with the institution and the IRB to get things done under the circumstances."

The NYU Langone IRB kept in contact with OHRP and apprised regulators of the backup plan. "We wanted to make sure we were conducting business within the framework," Czeisler says. "They had some understanding of how to address the institutions after [Hurricane] Katrina." Czeisler confirmed his IRB's plan with OHRP's senior leadership and also asked for input on specifics. With the organization's input, the NYU Langone IRB kept operations and protocol review running by prioritizing the protocols with greater than minimal risk, and had more flexibility to delay minimal risk protocols.

• **Plan for relocation of study staff and study participants.** "We think about the IRB and its operations, but we also want to think about the subjects. If they're on a protocol and need

to receive the intervention and they might need to come in for dosing or for tests," Speers says. "It's important to have a system in place where the IRB and researchers can plan who will be affected by temporary closing and have to make arrangements." Other arrangements include identifying nearby or affiliated facilities that are still operational and can accept investigators and clinical research subjects.

• **Be prepared for the unexpected.** Even the best continuity plan won't prepare for everything, so be on the lookout for new solutions. For example, when BRANY staff found their offices had electricity but no Internet access, quick thinking and a cell phone got them back online. "One person in our office made her phone a hot spot, and we were able to use that — something else we now put in our disaster plan," Irvine says.

When staff members with electricity in their homes opened their doors to colleagues who needed work space, BRANY identified that as a backup plan. "We were thinking of having hubs where we could say, 'If you're located in close proximity and have no power, there are people willing to let you come over to continue operations,'" Irvine says.

Since BRANY's facilities were unscathed, Irvine's team reached out to other IRBs in the area who may have needed a place to work. "We also did try to reach out to places that we knew were affected to see if people wanted to collaborate and needed an IRB to review something and we would try to work that out. No one took advantage, but we wanted to let them know we were available as a resource," she says.

Staff members need support, too

Since many IRB staff members had homes damaged and lives shaken up by the storm, nerves were frazzled and focusing on work was often difficult. According to Irvine, going into the office was a stress reliever of sorts.

"People were feeling like it was a safe zone, in a way — people could come in and charge everything up," Irvine says. "Some people had to bring their kids because schools were closed, so kids were in the office intermittently. Everyone was just open to thinking creatively and keeping the work moving."

Czeisler notes the dedication of the IRB and staff members in the face of the storm. "One of the fascinating aspects of this entire ordeal was observing not just the camaraderie but the spirit exhibited by some of the IRB members, acting as if it was their own home affected by the storm and going out of their way to make sure investigators who evacuated would have access to their records," Czeisler says. "The number of individuals that volunteered and helped remove samples and research records was amazing. It made quite a few people proud of the level of commitment to the program." ■

CNE/CME OBJECTIVES & INSTRUCTIONS

The CNE/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.

Physicians and nurses participate in this continuing education program and earn credit for this activity by following these instructions.

1. Read and study the activity, using the provided references for further research.
2. Log on to www.cmecity.com to take a post-test; tests can be taken after each issue or collectively at the end of the semester. First-time users will have to register on the site using the 8-digit subscriber number printed on their mailing label, invoice or renewal notice.
3. Pass the online tests with a score of 100%; you will be allowed to answer the questions as many times as needed to achieve a score of 100%.
4. After successfully completing the last test of the semester, your browser will be automatically directed to the activity evaluation form, which you will submit online.
5. Once the completed evaluation is received, a credit letter will be e-mailed to you instantly. ■

COMING IN FUTURE MONTHS

- Improve how research risk is reported to subjects
- FDA offers new guidance on IRB responsibilities
- Coverage of the 2013 AAHRPP conference
- Electronic system assists with IRB transparency, efficiency
- IRB has prize-winning best practice in compliance/education

CNE/CME QUESTIONS

1. A standard informed consent form might include which of the following sections?
   A. Introduction, purpose, procedures
   B. Benefits, risks/discomforts, confidentiality
   C. Compensation/payment, rights of the subject, questions
   D. All of the above

2. Which of the following would not be a good question to ask IRB members during a self-evaluation process?
   A. How would you rate the quality of your protocol reviews?
   B. How would you rate the quality of your contributions to IRB discussions?
   C. Both A & B would be good questions to ask members
   D. None of the above

3. Which of the following is a significant contributor to investigators' misconduct or wrongdoing in human subjects research?
   A. Low salaries and long hours
   B. Stress
   C. Lack of appropriate mentoring
   D. Narcissism

4. When preparing for weather emergencies, federal regulatory bodies do not need to be informed of an IRB's situation.
   A. True
   B. False