

# IRB ADVISOR

*Your Practical Guide To  
Institutional Review  
Board Management*

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## Do you have measures in place to protect student participants?

*IRBs should monitor psych student subject pools*

It's a staple of undergraduate psychology studies — the research requirement, in which students agree to sign up for surveys and other low-risk psychology research activities in exchange for academic credit.

Because such credit is often required to pass introductory psychology courses, IRBs should take a special interest in how the student subject pool is run, says **Bradley Waite**, PhD, assistant chair in the psychology department at Central Connecticut State University (CCSU) in New Britain. Waite also is chairman of the university's human studies committee.

One of an IRB's chief concerns should be that students have a reasonable alternative to participation in studies to avoid any potential coercion, say Waite and **Laura Bowman**, PhD, a professor of psychology at CCSU and also a member of the committee.

The American Psychological Association's code of ethics states that "when research participation is a course requirement or an opportunity for extra credit, the prospective participant is given the choice of equitable alternative activities."

"Here at Central, they have the option of being a participant in a study of some sort, or they have another option such as writing a paper," Bowman says. "Some other universities have other sorts of requirements — their students can view a film or go on a field trip. As long as they have options so that they're not coerced into being participants."

### **Participation provides benefits**

Waite and Bowman have authored studies looking at the benefits students derive from participating in psychology studies. They say students, particularly those who go on to be psychology majors, reported learning a lot from the process of being involved in psychology research.

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#### Editorial Questions

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Call **Alison Allen** at (404) 262-5431.

When the student subject pool at CCSU was first discussed about a decade ago, Waite says the human studies committee asked its developers to give the committee a proposal for how it would be run.

They first dealt with the critical issue of ensuring there would be adequate alternatives to actually volunteering for studies.

"If the psychology students were required to earn research credit, they need a decent alternative to do that was equally demanding — not more demanding and not less demanding, but something that would be reasonably attractive as an alternate for those people who didn't want to participate in the research studies," he says.

Bowman says students currently must earn four units of research credit, which translates into about two hours of research participation. Typically, it requires a combination of different studies or research activities.

"Some studies only require 10 minutes of time and others require a little bit more," Bowman says. "They get more credit for those that require more time. Most of our studies are about one to two credits, so that means about half an hour or less [total time]."

Accordingly, students who choose instead to read about a study and write a paper are told that they should put about an hour's worth of effort into the process, in order to earn two credits. Waite says students are told the finished product doesn't have to be a final, polished term paper.

"I've gone to some IRB conferences where I hear stories of universities requiring these 20-page papers, which clearly lends itself to being problematic in terms of coercing students in the direction of participating in the studies," he says. "We do give a lot of thought to the equivalency, and we think what we're doing is fine with respect to that."

Students who do choose to participate in studies receive credit as long as they show up at the appointed time and place. When they see the study itself, they can decide at that point to withdraw and still receive research credit, Bowman says.

As with other research, the investigator must inform the students about the study, how long it will take to complete and any risks associated with participating, and get their consent, Bowman says.

Students must be told that they can withdraw without penalty and be informed of any benefits, including rewards or incentives.

Bowman says those rewards are typically few and small, so undue compensation for participation is rarely an issue.

"Most of our research here is being conducted by advanced undergraduate or graduate students," she says. "They just can't afford to pay them. Sometimes they have an incentive — a free pencil or something."

### ***Underage students***

Another important issue for the human studies committee has been the potential for 17-year-old students to be involved in the student subject pool, particularly during the fall semester, when some incoming freshman haven't yet turned 18, Waite and Bowman say.

Waite says the psychology department provides a letter to parents of those students describing the nature of the studies being conducted. Parents are asked to give permission for the student to participate, either on a study-by-study basis, or blanket permission for any studies while the student is in the pool.

Bowman says students under 18 must show the parental permission form to the researcher to verify that he or she is allowed to participate. "We try to make sure that any study that would go under the blanket permission was an absolutely no-risk study," Waite says. "It's not that hard to do, as long as people are willing to cooperate."

After participating in a psychology study, Bowman says students are debriefed, especially if any sort of deception was employed in the research. Researchers must protect students' confidentiality by securing records.

"Most of the studies we conduct are anonymous — researchers don't even record student names or numbers," Bowman says. "There are a few, of course, where you have to track them. But in those cases we make sure the researchers are using procedures to maintain confidentiality. They have to make sure the records are kept in a locked drawer in a locked office or something like that."

Waite says an IRB reviewing studies that involve the student pool should definitely look at those student subjects differently than the general population when it comes to risk and benefit.

"On one of our forms, we ask for the possible benefits, and we look at whether there are some educational benefits that students get out of it," he says. "If you're requiring that people participate in some sort of research-related activity —

whether it's reading about studies and writing about them or participating in them — one of the goals that would come out of that is that we hope students who participate get some educational benefit out of it." ■

## **Flexible continuing ed meets varied needs**

*Something for everyone's skill level and schedule*

It can be a challenge to design a training program in human subjects protection that can meet all the needs of varied researchers — from biomedical to social-behavioral disciplines, from introductory courses to advanced topics for experienced researchers.

Officials at Case Western Reserve University in Cleveland have taken up the challenge, designing a flexible program that mixes established basic courses with guest speakers, seminars, and on-line offerings to give researchers the ability to take courses when and how they want.

**Christian LaMantia**, assistant vice president in the Office of Research Compliance at the university, says the Continuing Research Education Credit (CREC) program was developed in response to requirements that the university provide documented training in a variety of research areas. She says her group started with human subjects protection, launching the program in 1999 and setting September 2000 as the first deadline for training.

Case Western began by requiring all investigators and key personnel to study Dunn & Chadwick's manual *Protecting Study Volunteers in Research*, which includes a multiple choice test. They then began looking at options to meet NIH's requirements for continuing education.

"Our group started thinking, 'OK, we did this, it doesn't seem to make sense [review the manual] again,'" she says.

### ***Meeting social-behavioral needs***

At the same time, LaMantia was hearing from researchers outside of biomedical disciplines who felt that the manual wasn't specific enough to their areas of study.

"We cover people who do anthropologic observations, Psych 101, and the feedback we got from our faculty and our researchers was that although the [test] was easy to take, a lot of peo-

ple were upset that things didn't actually apply to them. For example, there were FDA sections where a lot of people don't do FDA-regulated research.

"Thinking through a continuing program, we wanted to make sure it would be meaningful," LaMantia says. "And to do that, it had to have options for people who do hundreds, if not thousands, of specific types of research. They're all each in their own worlds."

The team asked, "How could we make this meaningful?" The answer, as it developed, was CREC, a continuing medical education program that requires key human subjects protection personnel to earn a set number of credits every three years.

The credits could be earned by attending one of a few dozen seminars offered at Case Western each year, or by taking on-line courses offered by different institutions, or by attending other programs such as a seminar at a professional association conference.

The CREC program is administered on-line, with links to outside tutorials and other programs, and with units of credit assigned to a participant's CREC account when the activities are completed.

LaMantia says Case Western next turned its attention to another group of researchers seeking more specialized instruction — experienced researchers, who wanted meatier fare than the standard human subjects protection training available to everyone.

"They'd already been through the Belmont Report, the Helsinki, all the basics of informed consent," she says. "They wanted to talk about institutional conflicts of interest, what you do when you have an investigator-initiated study, what are your responsibilities as a sponsor. How do you know that your informed consent process was effective?"

Using an NIH human subjects research enhancement grant, Case Western set out to meet the needs of the experts in the field, creating an on-line program of advanced seminars on cutting-edge human protections issues.

Because such events can be hard to schedule, they created digitally recorded seminars by nationally recognized experts that CREC participants could access via the web.

"We digitally record them and then create an associated quiz or learning tool that goes with the videos," she says. "Right now, we have three sets of series, one on adolescents and children,

one on investigator-initiated research, and the other on ethical dilemmas in international research.

"People can watch the series, they can print out the handouts on their own time, and to earn credit within our documented program, they can take these quizzes, which can automatically connect them to our system and credit their account," LaMantia says. "In a sense, the goal of the project is to take this expert-level training home to our investigators and allow it to be accessible to everyone."

Because the program received NIH funding, Case Western has designed it to be accessible publicly to anyone with a media player, although no one can receive CREC credit without an open account. To view Case Western Reserve University's on-line Continuing Research Education Credit program, visit [ra.ra.cwru.edu/research/orc/crec/index.cfm](http://ra.ra.cwru.edu/research/orc/crec/index.cfm).

LaMantia says the program is a tool not only to improve education locally at Case Western, but to share with other institutions that might not have the same resources.

Through a second NIH grant, Case Western is developing relationships with other smaller institutions, such as unaffiliated hospitals or social science institutions, to share its human subjects protection education tools.

Through those relationships, they could become CREC members, with program content customized for their own institutions, "so they don't have to start out from scratch like we did," LaMantia says.

## **Technology challenges**

She says that creating the content was a "huge, huge challenge," primarily because of start-up problems associated with the new digital media technology they were using. Partly because of that, she's always looking for other sources of new seminars and on-line information to provide new content for the CREC program.

"I go through sister institutions' web sites, do Google searches for a lot of the on-line things," she says. She says institutions such as the Office for Research Integrity web site also can be a source of good content.

In many cases, such as Case Western's program, other on-line programs created with NIH money are offered free to other institutions.

Unfortunately, much of that content is still focused in the area of biomedical research, with

social-behavioral content being harder to come by.

“But I think there is a push toward getting more behavioral science tools out there to train people,” she says. For example, LaMantia says Case Western wants to host a segment on Internet research, including such topics as how to recruit subjects and how to ethically be involved in chat room discussions.

One of the technical challenges of creating the CREC program has been maintaining individualized accounts for the 3,000 to 4,000 researchers and others who use it. LaMantia says that because of privacy concerns, accounts are not linked to Social Security numbers but to another unique identifier so that the proper person is credited for taking the on-line courses.

In offering courses on-line to those inside and outside the university, LaMantia says her department also now finds itself running a data management program in addition to all its other duties. A lot of other institutions have firewalls in the computer systems that make it difficult to offer the technology across institutional boundaries.

LaMantia says she’s considered the idea of burning digital seminars onto DVDs in order to distribute them more easily.

The CREC program has evolved, retooling its web site and moving to use the Collaborative IRB Training Initiative (CITI) on-line education program created by the University of Miami for the basic training component.

The seminar program continues, with recent topics including confidentiality and privacy of electronic records in human subjects research and informed consent in research involving children.

LaMantia says response to the program has been enthusiastic. “The feedback we get from people who participate fully is they love it,” she says. “They love that they can take something that’s meaningful. They love that the content is current, which is a struggle that we have with HIPAA and with everything else changing.”

In fact, the complaints they do get are now from people who say there are almost too many choices for their continuing education training.

“The same people who were saying one size doesn’t fit all now are saying they have too much to choose from, that they want to go back to the 50-point multiple choice test, because it was defined. ‘Meaningful’ takes more work on their part.” ■

## Family medicine group suggests guidelines

*Recommendations cover three areas*

Research in family medicine is a diverse field, encompassing everything from practice-based research to educational studies to research involving communities such as American Indian reservations. Because of this diversity, and because much family medicine research differs from the typical clinical trial, many researchers in the field find existing guidelines for protecting research subjects hard to apply, says **William Hueston**, MD, professor and chair of the Department of Family Medicine at the Medical University of South Carolina, Charleston.

In an effort to address that problem, he says the Society of Teachers of Family Medicine (STFM) received funding from the Association of American Medical Colleges (AAMC) and the Office of Research Integrity (ORI) to create its own human subject protection recommendations for primary care researchers.

“In primary care disciplines, particularly in family medicine, we tend not to do as many randomized clinical trials, but instead focus on things that involve participants in the community,” Hueston says.

“What we proposed to the ORI was to pull out those areas that family physicians in particular and primary care doctors more generally do in research,” he says. “Let’s see what the issues are that have to do with both data integrity and participant protection.”

The resulting guidelines were presented last year at STFM’s annual conference, and Hueston says they have been accepted for publication in an upcoming issue of the society’s journal, *Family Medicine*.

The panel that convened to write the guidelines focused on three areas requiring attention: educational research, practice-based research networks (PBRNs) and community-based participatory research.

Of the three, Hueston says the issues involved in educational research — the study of different educational interventions and their effects on students — were the most straightforward and most easily resolved.

“I think most people would agree that people participating in those endeavors need to be informed of what’s going on, to give permission

for the use of the data, etc.," Hueston says. "But it's a bit of a stretch for some of the educational folks who wonder; 'Wait a minute, if I change a lecture do I have to get permission from students?'"

While the requirements are not that strict, Hueston says students who are the subjects of data collection in research need to be advised of that fact and considered research participants.

"You need to give informed consent where applicable and this needs to go to IRBs," he says.

Hueston notes that an audit of educational research studies submitted for publication in *Family Medicine* in 2004 showed that 90% of them had not undergone review by or received exemption from an IRB. He says he was not surprised at those numbers.

The new guidelines call for all educational research studies to be submitted to an IRB for review, and for researchers in this field to receive training about regulations regarding human subjects protection.

*Family Medicine* itself announced last year that authors submitting a manuscript to the journal must include a statement indicating that it has been reviewed or exempted by an IRB.

### **Practice-based research issues**

Practice-based research networks (PBRN) of physicians' offices give rise to other issues of research participant protection. Hueston says that many PBRNs operate at very different levels of sophistication. At the high end of the scale are sophisticated national research networks that work with IRBs to ensure projects are well-designed, physicians and staff are well-trained, and the resulting studies are scientifically valid.

"But there are many smaller research networks with only a few practices or a handful of groups, where the level of sophistication may not be very high, and they may be engaging in research that really isn't going to produce anything that's terribly valid," he says. "In which case, there's really no justification of any risk."

Another issue in research conducted within PBRNs is the fuzzy line between what's considered research and what's considered quality improvement in a practice.

"I think at an individual practice level, people are beginning to get a handle on what's QI and what's research," Hueston says.

"The problem occurs when you bind people together in a network and collect data from

multiple sites. Now is it QI or is it research? It's a difficult question."

In general, he says, when a network applies existing knowledge to its patients to improve care, that's quality improvement. An example would be implementing a new technique that has proved to be successful in published studies.

"But generally, people use the criterion that if it is intended to be published, to demonstrate new knowledge, or to disseminate the application of existing knowledge, then it's research," Hueston says.

The PBRN guidelines offered by the STFM panel include:

- assuring that PBRNs' research projects will provide valid and meaningful scientific information;

- streamlining informed consent, where appropriate, in projects with reduced risk, and allowing for central IRB approval or acceptance of consent forms approved by other certified IRBs;

- divulging any conflicts of interest by all investigators in a PBRN project;

- collaboration by investigators, clinicians, and regulators to better define the boundary between research requiring IRB approval and quality improvement projects.

"I think if we set these as guideposts, then even the less-experienced networks can say, 'OK, we really need to work towards them,'" Hueston says.

"I'm hoping this improves the overall caliber of PBRN research, particularly among those smaller networks that may not have as much research sophistication or the resources that they've been able to put into this in the past."

### **Community research raises tough issues**

Of the three areas the STFM panel focused on, Hueston says the issues raised by community-based participatory research were the most difficult.

An example of this type of research might include researchers going into a community such as a Native American reservation or a small, rural town and conducting a needs assessment with residents to identify health care problems and study possible solutions. Researchers might study the success of a stop-smoking campaign or a project in schools to teach healthy behaviors.

The introduction of that third party — the community, in addition to researchers and

individual subjects — creates problems in designing studies, Hueston says.

“The town’s perspective may not be shared by the researchers, and how you actually implement that intervention can be ethically complex,” he says. “Does everybody in the town have to consent before you try to improve the health of the community? Who has to say yes, and who speaks for the community? There’s no elected health spokespeople, you have to go with key informants, people who seem like they’re leaders and opinion experts and hope that you’ve got the right folks.”

When it comes time to interpret the data, the community may have a different take on the data collected and may have a stake in wishing to protect its reputation, Hueston says.

“Is it the researchers’ data or the community’s data? And how do you collaborate to report what happened, keeping confidentiality and protecting the reputation of the community as well?” he says.

“Those are all issues you don’t find in the manuals for controlled randomized trials or benchtop research.” These tend to be issues that IRBs have little or no experience with, he says, because their emphasis is on risk to individuals.

“IRBs will have no idea what’s going on here,” he predicts. “The town doesn’t have an IRB. The subjects or participants may have different perspectives than the IRB in an institution many miles away in a different cultural milieu.”

All of these issues caused considerable debate on the panel, Hueston says.

“How far do you allow the community to decide what gets published and what doesn’t? Do they have veto power if it doesn’t look good to them? Where really do you draw the line?”

The panel’s recommended guidelines include: — including protection of the community and its possible stigmatization as part of IRB oversight of such studies.

— requiring review and approval by community representatives in addition to the IRB.

— review of the plan for disseminating findings from the study, particularly results that may be sensitive.

— protecting data from the research, and making it available for additional analysis only with consent of the participating community and researchers.

Hueston says that this area will require further consideration and debate.

“I think that’s the area that will require the

most work in the future to be sure that these are played out and that people adhere to them,” he says. “It has the potential for a lot of harm for participants if not ethically performed.” ■

## Improve SAE reporting with electronic submission

### *Reduce unnecessary reports*

One of the bigger headaches for IRBs is having to sift through hundreds or thousands of unanticipated problems submissions when most of these should never have been reported. The Human Studies Committee at Washington University School of Medicine in St. Louis has developed an electronic submission process that has addressed this problem.

In 2003, prior to the system’s inception, the IRB reviewed more than 11,000 submissions of unanticipated problems, deviations, etc., says **Diane Clemens**, DC, CIP, manager of research. Thanks to the system’s screening and review process, the IRB reviewed 6,664 fewer unanticipated problems than the previous year, a 60% drop in volume, Clemens says.

“This is a problem in the IRB realm where we’ve historically gotten inundated with a lot of reports we didn’t need to see and which should have just been reported to sponsors,” Clemens says.

The first person to see the unanticipated problems that have made it through the screening process is one of the four reviewers — all of whom are RNs, Clemens says. However, if the event is a death, it is automatically routed to the IRB chair, she notes.

Previously, unanticipated problems submissions were reviewed by four volunteer subcommittees, each consisting of 20 people who met once a month. The implementation of the electronic system and change to staff reviewers is a more efficient and effective process because these individuals do reviews every day, Clemens says.

“We’ve seen such a drop in the review volume because the system will screen out external events that do not cause a change in the protocol or consent or increase the risk to participants,” Clemens says.

Here’s how the system works:

- **All initial serious adverse events (SAEs) go through the electronic system** where they are

divided between internal and external SAEs, Clemens says. “We still have a significant number of SAE follow-up reports that are submitted on paper — some 3,619 — but these are dwindling,” Clemens notes.

Investigators log in and follow on-screen directions for reporting SAEs and other events, she says.

The on-line prompter will ask the investigator whether the risk to participants increased, whether there is a change to the protocol, and whether or not subjects need to be notified of additional risk, Clemens explains.

“Typically, we see if it’s a long-term risk that’s identified, then the participants need to be contacted,” Clemens says. “If it’s something where after the first dose you are at increased risk for this reaction, but all people taking it at our site have already taken the first dose, then the need to contact them is no longer there because they’re no longer at risk.”

When investigators log on, they’ll see a screen that has a list of all of their studies, both open and closed. They select which study the report pertains to and the next screen asks them to identify the type of submission they will make, Clemens explains.

“The initial page will give the specific item, unanticipated problems, external SAEs, a follow-up report, data monitoring report, a deviation, and we have another problem section,” Clemens says. “The most common thing we see is submission of unanticipated problems.”

Investigators select the correct path and follow it through the electronic process.

For instance, for unanticipated problems, the process requests information about the timing of the event and the system will calculate whether or not the submission is being made within the appropriate timeframe, based on reporting guidelines that are pulled from the regulations, Clemens says.

The idea of this lengthy screening process is to assess these reported incidents against a very narrow definition of what needs to be submitted to the IRB, and these are consistent with the recent guidance released by OHRP, Clemens says.

• **System establishes criteria for what should be reported.** The Web page following the prompt about time frame is the screening tool, which helps investigators determine whether or not the event they are considering reporting truly needs to be reported, Clemens says.

The screening form outlines three criteria to determine whether something is an unanticipated problem or serious adverse event that requires submission to the Human Studies Committee and OHRP as follows:

- The event is serious;
- The event is unexpected;
- The event is reasonably related to the research.

If all three criteria apply, the investigator is directed to continue with the submission, and if they do not, then the investigator is told that the event does not meet the institutional requirements for reporting and should exit the system.

Since investigators often report events not meeting these three criteria to the IRB per instructions from sponsors, the next prompt also says, “If the sponsor of the study is asking you to notify the IRB of an event that does not qualify for reporting, please send the following letter to the sponsor as notification of our review policy.”

The investigator could click on the prompt for an SAE review policy screen and print a ready-made letter to send to the sponsor.

The screening page also includes definitions of the criteria for investigators who are uncertain of whether their events qualify. For example, the definition states that an event is serious if it adversely alters the relationship between risks and benefits and includes events that either result in or require intervention to prevent the following:

- Inpatient hospitalization or prolongation of hospitalization;
- Life-threatening reactions;
- Result in persistent or significant disability/incapacity or permanent harm or disability (either physical or psychological);
- Jeopardize the subject;
- Congenital anomaly/birth defect in the offspring of research participant;
- Breach of confidentiality that may have a negative consequence;
- Death.

“Part of our system that’s pretty nice is it’s set up as a split screen with guidance to investigators on one side,” Clemens says. “And on the other side of the screen they’re working on questions we’re asking them.”

If an event meets all three criteria, then the investigator is given a link to a directory of events. They can choose whether it’s related to allergy/immunology, general cardiac, etc., she says.

"Then there's a find button and it pulls up all the terms related to cardiac, for example," Clemens adds. The idea is that the system limits the numbers of terms and helps investigators keep better track of events that have occurred in a study, linking them together as needed.

"It provides some consistency and is especially helpful if you have several different coordinators who may be entering SAEs for one particular study," Clemens explains. "What the system will do is track the number of incidences of a particular event and calculate the percentage of occurrence based on the number of participants."

- **Investigator adds pertinent information.**

The electronic system's next prompt is for similar SAEs that have occurred at the institution, as well as other institutions, Clemens says.

"There may be events that are not exactly the same, but they have a similar process, or they may be somewhat linked to this event," she says. "Also, the investigator may have gotten reports from other institutions, which are not something he had to submit to us, but it may be good information to have."

Likewise, the system asks investigators to provide additional comments, including descriptions of related events. For example, there could be a different study using the same drug resulting in an unanticipated event in a different population, but the metabolic process could be the same, Clemens says. "Investigators have the flexibility to elaborate on what has happened," Clemens says.

Then the system asks for information about when the SAE occurred and when the principal investigator was notified of the event, and that tells the system whether the report is made within the appropriate timeframe, Clemens says.

The next thing the system asks is what changes need to be made in light of the event, including possible changes to the informed consent form, changes to the protocol, and if these are changed they are sent to the IRB in attached Microsoft Word documents, she says.

"We have received reports from investigators saying, 'I intend to revise the consent form and I will submit it at a later date,'" Clemens notes. "The event is reported on time, and we've reviewed and considered it, but we'll hold it open until we receive the final piece of the revised consent form."

If an investigator chooses not to revise the consent form, he or she is asked to provide a rationale for why the change is not needed, Clemens adds. ■

## IRB streamlines process to improve response time

*Reviews went from 24 days to 17 days*

Intermountain Health Care Urban South Region of Provo, UT, revamped its IRB process with a goal of reducing its lengthy response time and improving quality in IRB submissions.

After making changes that included hiring an IRB staff person, purchasing new software, and improving education, the institution was able to reduce the 24 days it took on average to bring a protocol from submission to IRB review to 17 days, and the average number of days from the IRB meeting to IRB correspondence was dropped from 22 days to five days, says **Katreena Collette Merrill**, RN, a nursing practice and research coordinator at Intermountain Health Care.

The decrease in the days it takes the IRB to respond post-meeting was directly related to having the process computerized and the hiring of a dedicated IRB coordinator, Merrill says.

"And we had the expectation that we wanted to have a quicker turnaround," Merrill says.

Merrill describes how the institution improved its process with these guidelines:

- **Address problem areas.** When Merrill became the research coordinator at the institution, there were no formal policies, procedures, or checklists, she says.

"And not only was the initial response time from when they submitted the application slow, but the quality of submissions wasn't very good because investigators didn't know what we were looking for," Merrill explains. "So we went at the problem from a myriad of approaches."

First, a goal was set to reduce the time from submission to review by the IRB, and an IRB staff person was hired, Merrill says.

Then, the IRB purchased software and began an electronic system and then changed the entire filing system, Merrill says.

"We were still using hard copies at first, so we organized the filing system by year and the number of the study, and the first study submitted in 2005 was labeled 2005-01," Merrill explains.

- **Develop checklists.** Checklists are used to help reviewers find omissions and mistakes in IRB submissions.

One checklist includes information about protocol submission related to NIH guidelines, and it asks questions, such as these:

- What was the stated hypothesis?
- What was the design of the study?

Another checklist relates to the FDA, and it goes through all of the different FDA requirements.

A consent checklist asks whether the consent document indicates that the subject has the right to withdraw, Merrill says. "Does it have the contract number for the principal investigator," she adds. "What is its readability on a readability scale?"

The consent checklist contains standard information of what should be on a consent form and in the protocol, Merrill says, including the following:

- If someone is going to use pediatric patients, is there an assent attached?
- If someone is going to be working with patients who do not speak English, is there translation service available?

"We would take those checklists and give them to our primary reviewer, and the primary reviewer uses the list to check off items and say, 'They don't have this or that,' or 'I couldn't find this information,'" Merrill says. "It's a much, much easier process."

The IRB coordinator has received training, and now she understands the submission process and can use the checklist to make sure investigators have completed their information before protocols are submitted to the IRB, Merrill says.

"She can tell them, 'I can send this to the IRB, but you don't have this information, and you might want to do this before you submit it,'" Merrill says.

Some of the IRB review process bottlenecks were caused by repeat mistakes on the part of investigators.

- **Make changes as necessary.** As an IRB process is revamped, it's important to make adjustments and changes as new issues arise, Merrill notes.

For example, one physician who worked on newborn intensive care unit studies would omit an approval signature from the ICU manager on the submissions, and so a section was added to the submission form, saying that the investigator needs to obtain approval from these people prior to submitting the protocol to the IRB, Merrill says.

"We've made a lot of changes," Merrill says. The IRB coordinator, for instance, was a part-time position at first because the IRB is small, with only about 75 open studies, Merrill says.

Now, the IRB coordinator handles IRB work for the entire Intermountain Health Care system, which includes 22 hospitals, she says.

"With a central system, the IRB coordinator is half-time for us, and the other half of her time is for another region," Merrill says.

- **Move to an electronic system.** "We've created a virtual system where the IRB coordinator sends me all of the information and types the expedited review letters electronically, creating a PDF document, so it can't be changed," Merrill says. "It still has my signature, and no one can attach or un-attach it."

Everything is available on a web site, as well, she says.

Although the IRB coordinator is located an hour from each of the two research offices, the electronic system makes it as easy for the coordinator to work with investigators, IRBs, and research staff through telecommuting, Merrill says.

"If someone submits electronic data, then it's all electronic from the beginning," Merrill says. "But if someone submits a hard copy, it's copied and scanned and made into a PDF file."

Study changes that need expedited review can be seen by the IRB's chair or vice chair, Merrill says. "We didn't have a vice chairman when we started all of this, and then we found out when the chairman goes out of town, you're stuck and can't do anything," Merrill notes. Since this slowed down the system, a vice chair position was added.

- **Provide formal training and education.** After the first changes were made, the institution held a meeting for the IRB and staff and went over the checklists, Merrill says.

All protocol and checklist templates were put on a CD, and there also were hard copies for distribution, Merrill says. Now all of the information is available on a web site, she adds.

The formal training was done at a two-hour meeting, offered several times so all investigators and coordinators could find a convenient time to attend, Merrill says.

"We introduced a whole binder of hard copy information and introduced all policies and procedures and checklists," she says.

The training session explained why the institution was making the changes and what the goals were, Merrill says. "They weren't too happy at first about the electronic submissions because some were doing a lot of protocols and didn't want to submit electronically, but we reassured

them that it would decrease the response time," Merrill says.

Investigators weren't required to attend the meetings, but they did have to pick up the training material and review it, she says. And the institution also required every person listed on a study, including principal investigators, co-investigators, study coordinators, and the people handling informed consent, to complete on-line human subjects research training coursework and receive a certificate, or else their study would be closed, Merrill says.

"Now they can't get an IRB application without having the training," Merrill says.

Some of the future plans for the streamlining process is to improve the electronic submission system to make it more user-friendly, Merrill says.

"We still want to do more training for new investigators," she adds. For example, the institution could offer courses on how to write protocols, Merrill says.

Also, the IRB may eventually become entirely electronic with laptops for members, and the institution might provide its own research training classes for certification, Merrill adds. ■



## Nuclear terror threats spur treatment studies

Amid growing concern that terrorists may strike with a nuclear weapon instead of a biological one, the government is fast-tracking programs to develop medical countermeasures against radiological and nuclear threats.

The National Institute of Allergy and Infectious Diseases (NIAID) has issued more than \$47 million for grants, contracts, and interagency agreements as part of a new NIH research program on medical countermeasures against radiological and nuclear threats.

Eight universities or research institutes have received grants to establish Centers for Medical Countermeasures Against Radiation. The centers will focus on basic and applied research to develop new products for measuring radiation exposure, to protect against exposure, and to minimize and treat the effects of exposure to a wide range of radioactive compounds. The research centers are being asked to develop biodosimetry devices to measure radiation exposure, therapeutics to treat short-term and long-term symptoms of radiation exposure, as well as products that can prevent or mitigate the effects of radiation exposure.

Funding for the centers totals about \$28.7 million for fiscal year 2005. NIAID plans to fund the centers for five years.

In addition, the University of Maryland School of Medicine has received a \$9.3 million contract to evaluate promising compounds to prevent, reduce, or treat symptoms of radiation exposure.

NIAID also earmarked funds to support projects focused on protecting the immune system from radiation or restoring the immune system following radiation exposure. Products that provide pre-exposure protection could be used by first responders to prevent bone marrow damage, while post-exposure products would help restore immune system cells that are formed within bone marrow.

The research push comes as reports surface that the United States remains vulnerable to nuclear terror. The Sept. 11 Commission recently used the term "insufficient progress" in assessing the federal government's efforts to thwart nuclear or radiological terrorism. In a follow-up report into its original inquiry into 9/11, the commission urged the Bush administration to make preventing nuclear terror the "top national security priority." ■

### COMING IN FUTURE MONTHS

■ Is state regulation of human subjects research above and beyond federal rules?

■ Protecting third parties in social-behavioral research

■ How should ethical breaches among international colleagues be dealt with?

■ A process for measuring IRB productivity

■ Improve compliance, educational, and liaison activities

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## CE/CME Objectives and Instructions

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.

Physicians and nurses participate in this medical education program by reading the issue, using the provided references for further research, and studying the questions at the end of the issue.

Participants should select what they believe to be the correct answers, then refer to the list of correct answers to test their knowledge. To clarify confusion surrounding any questions answered incorrectly, please consult the source material.

After completing this activity at the end of each semester, you must complete the evaluation form provided and return it in the reply envelope provided to receive a certificate of completion. When your evaluation is received, a certificate will be mailed to you. ■

## CE/CME questions

1. The American Psychological Association's code of ethics states that when students participate in psychology research as a requirement for course credit
  - A. They must not be exposed to any risk
  - B. The research must not be deceptive
  - C. They must be given a choice of equitable alternatives to research participation
  - D. None of the above
2. Because of their age, 17-year-olds are not allowed to participate in college student psychology pools.
  - A. True
  - B. False
3. Recommended guidelines for community-based participatory research include that IRBs should consider which of the following in reviewing proposals?
  - A. Risk to individuals
  - B. Risk to the community's reputation, including possible stigmatization
  - C. Privacy concerns
  - D. All of the above
4. Before an incident can be reported to a human studies committee and OHRP, it should meet three criteria. Which of the following is not one of the three criteria?
  - A. The event is serious.
  - B. The event is the result of a human error.
  - C. The event is unexpected.
  - D. The event is reasonably related to the research.

**Answers: 1. C; 2. B 3. D; 4. B**