IRB ADVISOR

Your Practical Guide To Institutional Review Board Management

AHC Media LLC

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Special Report: Cutting IRB costs in lean times

Hard times: How IRBs can cut costs without sacrificing service

Charge fees, cut paper use, reduce overhead

[Editor's note: This is the second part of a two-part series on how IRBs can cut costs during these lean budget times. States are forcing higher education payroll and departmental budget cuts across the nation, and IRBs likely will be impacted. IRB Advisor asked a number of IRB efficiency experts to discuss how IRBs can make do with fewer resources. In this month's issue we present a case study of how one university approached IRB cost-cutting. In the April, 2009, issue, there were stories on collecting outcome data and making your IRB more cost-efficient.]

Sometimes the best way to cut costs in the long run is to spend more money in the short-term. This is the philosophy behind the move to an electronic IRB submission system at East Carolina University (ECU) in Greenville, NC.

"When we look at what our costs are, it's always paper; it's always copying," says **Norma B. Epley**, MS, CIP, administrative director and department chairperson of the University & Medical Center Institutional Review Board at ECU.

Most university research institutions are experiencing state budget cutbacks, which have resulted in hiring freezes, Epley notes.

"With our research enterprise growing — and I believe it will continue to grow — and with the freeze on hiring, it's very important we utilize every bit of resources we have," Epley says. "So that includes even the processing of IRB applications and forms."

This is why the IRB and research institution have focused on the costs in time and paper of copying information, faxing forms, etc., she adds.

"I think most institutions are going to look toward electronic relief for those kinds of expenses," she says.

"Those are the areas we're really focusing on now," Epley says.

"How can we continue to provide the service we should be providing to our investigators and still meet the budget constraints we have?"

Therefore, Epley and staff are setting up electronic forms.

Fortunately for the IRB office, the university is providing the new computerized data management system free of charge to the IRB, she notes.

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"Part of the new system will have electronic IRB submissions built into it," Epley explains. "There will be in-house people doing it."

Once in place, the new system will provide electronic IRB agendas, as well as electronic submissions.

Epley estimates that about two-thirds of IRB members will immediately use the electronic system, and the remaining people will need paper copies, at least in the beginning.

"A third of our members are just not used to electronic forms," she adds. "Plus our community members may not have the resources to have a computer or to print-out anything."

An easier sell

The electronic system will be easier to sell to investigators because they have received National Institutes of Health (NIH) training on electronic submissions, Epley says.

"They're a very supportive group, and they'll want to understand and do whatever they can to help the IRB cut back on costs," she says.

Another cost-cutting move is to provide Web-based education, Epley says.

"Typically, we've had classes, seminars, workshops, and staff meetings that people attend," she says. "But that's an expense in human resources."

"So we thought we could cut back by providing education through electronic means where investigators and others can take the courses at their leisure or from their home, and they'd still meet the university's requirements," she adds.

"If we can provide information that's unique to ECU through Web-based training, it will allow my staff to focus on issues they need to focus on within the office," Epley says. "And, hopefully, that will mean we won't have to cut any services."

The IRB also will save money by offering in-house professional development opportunities, such as helping study coordinators become better regulatory specialists.

"There won't be money for professional development like there has been in the past, so if we can provide that in house it will be one of the greatest services we have to offer," Epley says.

Another strategy during lean budget times is for IRBs to charge fees for their services to protocols submitted by for-profit entities.

ECU has limited fees to industry sponsors, but does not charge for student research or for federally-funded or principal investigator-initiated research, she says.

"ECU has just initiated this," she adds. "It was in place, but we had never enforced it until March, 2008, and it has provided enough funds for the institution to hire me."

The fee income has made the IRB self-sufficient in terms of salaries, Epley says.

"So that was one way to help with the budget," she adds.

When IRBs and research institutions face difficult economic times, they also need to keep up staff morale through small, inexpensive gestures, Epley suggests.

"For instance, I'll buy lunch and have a game day for staff," she says. "During lunch, we'll play board games and card games."

It is up to managers, directors, IRB administrators, and upper administration to help individual employees realize how important they are to the organization, Epley says.

"We want staff to know this is a team effort and everyone has to chip in during hard times, but it will pass," she adds. "And when it does pass, there will be rewards."

Also, a simple thank-you can go a long way, Epley says.

IRBs also might improve staff morale and cut overhead costs by giving staff some flex time.

"As long as an IRB office is covered for its services, it seems to me that it may be beneficial to allow people to work flex time so that one day a week we're not hitting the utilities quite as hard," Epley explains. "This would mean having a day where people would work from their homes, and the IRB's phones would be transferred."

For institutions where some faculty appointments are for nine months of the year and so IRBs see less foot traffic in the summer, flex time especially would make sense during the slower months, she suggests.

"Perhaps you could allow someone to review applications and operating policies from their home because there are a lot of things that can be done when submissions are electronic," Epley adds. ■

Oversight IRB helps resolve issues

Committee provides networking, education

Large research institutions can improve IRB consistency, education, and networking by establishing an oversight board that will bring IRB chairs together at committee meetings.

The City University of New York (CUNY) in New York City has 20 IRBs handling research protocols at CUNY's many campuses across the city.

One way the diverse institution makes certain IRB members are aware of new policy and regulatory information is by having each IRB's chair meet as part of the institution's oversight IRB, says **Patricia MacCubbin**, MS, executive director of research conduct and special advisor to the vice chancellor for research at CUNY.

The oversight committee also serves as an appeals board and as the IRB for research initiated by the institution's central office, she says.

For example, if a librarian plans to conduct a system-wide research project, he or she will submit the protocol to the oversight committee for review, she says.

"We rarely have anything that rises to the level of a convened meeting review," MacCubbin notes. "A lot of what we do at meetings involves educational purposes."

Common problems

A regulatory or other issue that arises at one IRB might be something other IRBs will need to learn more about and eventually deal with. When the committee meets solely for educational purposes, then there is no vote and the meeting is not convened.

"We've only had one protocol that went to the convened meeting of the board, and it was about four years ago," MacCubbin recalls. "We made sure our nonscientist and community member were represented."

The oversight committee's meetings are held irregularly, but typically at least twice a semester, she adds.

"It's difficult to find a meeting time," she adds. "The trick is for us to try to find a day or week or month when we can get a good representation of IRB chairs there."

MacCubbin also views the oversight committee's role as one that involves networking.

"I bring the IRB chairs together, and they get to know each other and trust each other, learning how each IRB works and what they know," she explains. "The networking helps them understand where the other people are coming from, and it helps them learn to trust them."

The oversight committee's role as an appeals

board gives investigators an option to follow if their study is not approved by the IRB handling their protocol.

"If an investigator's study is not approved at his campus, then he can appeal at the campus level," MacCubbin says. "If it's disapproved again, then he can go to the CUNY-wide IRB and appeal."

The oversight committee will conduct its own review, and its decision is final.

"If they disapprove you, you're done because the administration does not get involved," MacCubbin says.

"It's an interesting appeals process," she notes. "We haven't had one go through the process yet in my five years here, but the faculty knows it's available." ■

Ask2-4U:

Training day: Recognize cultural differences

Effort includes 'one-on-one' training

Patricia MacCubbin, MS, executive director of research conduct and special advisor to the vice chancellor for research at the City University of New York (CUNY) in New York City offers some suggestions for educating researchers and IRB members in a large, diverse organization.

IRB Advisor: What are some of your strategies for training investigators at CUNY?

MacCubbin: Each of our campuses has a unique identity, and even though they are part of the university, they also feel independent. So it's a unique culture to deal with, and we have cultural issues: we go from one of the poorest, high-minority colleges to upper-level colleges with affluent students. We run the gamut from community schools to graduate schools.

So our IRB world also is interesting because some of the community colleges have very little research, maybe 10 to 30 projects a year, and the senior colleges could have 400 to 500 projects they're dealing with per year.

If an IRB doesn't have the opportunity to do a lot of reviews, it's a little more difficult for them to be up to snuff. We have to make sure they can be on top of everything and know particular pieces of their regulations. We use a multifaceted approach. One approach is to require everyone who does research and all IRB members or staff to take Web-based CITI [Collaborative Institutional Training Initiative] training modules.

Then the IRBs go out and do one-on-one training with people on their campuses, or they go into classrooms of certain disciplines that seem to have more interest or problems and they relay information to those particular disciplines.

IRB Advisor: What are your other training strategies?

MacCubbin: Some campuses have an open house where investigators can come in and talk with the IRB about problems they're having.

Also, each year I put on a one-day training session in the fall for IRB members and staff. It's styled like the PRIM&R [Public Responsibility In Medicine & Research] conference, but is much smaller. We have 225 IRB members and staff across all five boroughs of New York City, and the conference had almost 150 people attend it. It was open to other New York City institutions, and we had about 30 people attend from around the city.

We also have three sets of meetings: one is for our IRB administrators, and we talk about issues they have. And then we have a set of meetings for IRB chairs. Our 21st IRB is an oversight IRB, which is comprised of all of the chairs of the IRBs in one capacity or another. I call these people together on a fairly regular basis, and we talk about things the IRB chairs can pass on to their members.

The third piece is our IRB manager's user group. We're implementing a software program for electronic tracking, and we have user group meetings to discuss problems we find so we can get standardized across campuses.

We start analyzing it, talk with the vendor, and get problems fixed. When we see some systematic problems and realize we haven't trained people right, we call the vendor in to do more training. ■

IRB members: It takes all types for all boards

Continuing education is key

IRBs have to adhere to regulations on diversifying their board memberships, but specifically finding the appropriate expertise for any particu-

lar meeting and finding dedicated non-scientist members are major challenges IRBs face.

"To join a clinical research board is very intimidating; the science is intimidating," says **Charlotte H. Coley**, MACT, CIP, director of IRB educational programs at Duke University Medical Center in Durham, NC.

"Our IRBs attract a lot of retired scientists, which helps with finding community representation," Coley notes. "But it doesn't help with the non-scientist slot."

Being on an IRB requires time, dedication, and altruism since it's a volunteer position. So it's been difficult even finding clergy who are interested.

"Our meetings are long so that has made it a challenge for us to find someone who has five hours they can take away from their church time," Coley says. "Plus there is a lot of preparation time."

Duke has eight IRBs that meet monthly, plus a Rapid Response Board that meets as needed, Coley says.

"The IRB membership includes representatives from each of the clinical departments in the medical school, plus clinical research trainees, who are third-year medical students and residents," Coley adds. "The challenge was finding community and non-scientist members for the eight IRBs."

Duke University's solution to this dilemma is to create a different category of IRB membership. It's a composite category called a Collocative member that includes theologians, hospital chaplains, community members, study coordinators, hospital social workers, and non-scientists, Coley explains.

"For another twist, we said you could either be affiliated with the institution or unaffiliated with the institution," Coley says. "So someone who is retired and active in the community but who is serving on the board of the pediatric hospital could be an affiliated member of the IRB."

Each of the eight IRBs now has three or four members who are in the Collocative member category.

"There's strength in numbers, and they're not as intimidated or outnumbered by the scientists in the room," Coley says. "Some of the Collocative Members could be study coordinators who work at Duke, but who went to divinity school and got interested in working with clinical research."

For example, one IRB member has a master's in Christian education and also is a study coordinator who works in pediatrics, Coley says.

"I sent this person's resume to the Office of Human Research Protection (OHRP) and asked whether this person would be considered a scientist or non-scientist," Coley says. "The feedback I got from OHRP was that he was a non-scientist."

The key to finding community and non-scientist IRB members is to think outside the box and look for people who may have had careers in one area, but who have developed an interest in research later in their lives.

"I put out the word to our IRB members when there is a need for a new Collocative member, and I ask if any of their friends or people they know might be interested in serving on a board," Coley says.

Coley looks for potential recruits among her circle of friends, as well.

"I had one friend who had been laid off after a long career," she says. "I said, 'While you're job-hunting serve on the IRB."

Her friend liked being on an IRB so much that she ended up serving on two boards, Coley adds.

Some board members have brought in their neighbors or made other referrals.

The IRBs have had members who were retired telephone company employees, a florist, a lawyer, and professionals with backgrounds in regulatory affairs and research ethics, Coley says.

The retired florist had previously worked in research and survey design, Coley notes.

"We have one gentleman who is a retired film critic, and he's a very fine board member and reviewer," Coley says.

Another key element to finding and developing good IRB members is to provide comprehensive training and education.

"What we do for all board members that helps us retain them is to offer an orientation and continuing education program," Coley says. "Continuing education is especially important for community members."

There is a two-hour training session held monthly. It can be opened up to all IRB members when it covers a topic that might interest everyone. For example, when the new genome bill (GINA) was passed, an IRB vice chair, who has a PhD in genetics, spoke along with a faculty member from the university's genetics institute, she adds.

"It gives them additional tools and gives them an opportunity to meet together so they're not as overwhelmed by their responsibility or the process," she explains. "Then they begin to have fun as board members and begin to enjoy the

role."

The training covers clinical research, the different types of clinical trials, what data safety monitoring boards do, and the informed consent process among other topics.

"I've videotaped guest speakers who did presentations, and as new members join, I give them a workbook of DVD presentations and PowerPoint handouts," Coley explains.

IRB members begin to see the fringe benefits of meeting people in different university departments and involving themselves in an intellectually stimulating enterprise.

"The protection of research subjects is never dull," Coley notes. "There's always a slightly new and different twist with each study reviewed."

Another strategy for recruiting and retaining IRB members is to make some practical changes in how the IRB operates.

For instance, long meetings are a negative for both attracting and retaining IRB members. So Duke added extra IRBs so the meetings could be shortened to four to five hours, Coley says.

"We try to provide nice box lunches," Coley says. "The IRBs meet at 1 p.m. and run until 4 p.m. or 5 p.m. at the monthly meetings."

This strategy has worked well, and it's also opened the door for more involvement by those who seek more IRB time.

"Some of the Collocative members have asked if they could attend additional IRB meetings, so we have some members who serve on two or even three boards because they like it," Coley says. "We give them a free lunch, free parking, and a tray full of candy bars and crackers to provide extra energy as needed."

The boards' retention is high with most members having served for at least three years and some for as long as 10 or more years, Coley adds.

"We've had good retention for most of our Collocative members," Coley says. "If someone joins and leaves quickly it usually is because of a change in their life, like they moved away or started a new job." ■

IOM panel finds HIPAA, health research a bad fit

Recommends sweeping changes to handling privacy

An Institute of Medicine committee has proposed a bold solution to the vexing problem of trying to conduct healthcare research under the Health Insurance Portability and Accountability Act's Privacy Rule.

Don't do it.

The committee of ethicists, researchers and privacy experts recommends taking healthcare research out from under HIPAA entirely; instead creating a new approach to privacy protection that would apply to all health research.

"The committee's conclusion is that the HIPAA Privacy Rule does not protect privacy as well as it should, and that, as currently implemented, the HIPAA Privacy Rule impedes important health research," states the report, which was published earlier this year.

It outlines shortcomings of HIPAA: It doesn't apply uniformly to all health research; it overstates the role of informed consent in protecting privacy, rather than actual privacy protections; it conflicts with other regulations governing research; and it creates obstacles that can leave studies with biased samples and invalid results.

Sharyl Nass, PhD, study director for the IOM HIPAA project, says the IOM Committee on Health Research and the Privacy of Health Information didn't come to its sweeping recommendation lightly. A change of this magnitude would require congressional action, and mindful that that might not be feasible, the committee also made a number of suggestions for continuing to work with HIPAA, while improving guidance and clarifying provisions of the Privacy Rule.

"We did what we could to try to tweak the current system, realizing that that's the most likely thing to happen," Nass says. "But the committee thought it was very important to make the point that the way we're doing this is just not good."

Wendy Visscher, PhD, director of the Office of Research Protection at RTI International in Research Triangle Park, NC, was a member of the IOM committee. She says other countries have much stronger privacy protections than the United States, and hopes to see a similarly strong law here eventually.

"We knew that it was ambitious and would be very hard to implement because you had to get Congress involved and excited about it," Visscher says. "But we still think that eventually, that's what needs to happen. We felt like in good conscience, we couldn't leave it out of the (report)."

Applying to all research

The committee held hearings in 2007 and 2008, inviting researchers, privacy experts and others to comment on HIPAA and its effect on health research. It commissioned studies that showed researchers were being stymied by HIPAA's privacy provisions and that IRBs were implementing the Privacy Rule in widely varied ways.

Visscher says one serious flaw with HIPAA is that it doesn't apply to all healthcare research.

"HIPAA only applies to covered entities, so if you're an independent research organization like RTI, we don't fall under the HIPAA Privacy Rule," she says. "If you're doing privately funded research, you're not going to fall under the Privacy Rule."

In its recommendations, the committee called for all health research to be subject to a new system of privacy protections, regardless of funding or type of entity. HIPAA's privacy provisions still would apply to health records kept by providers, insurance companies and clearinghouses, Visscher says. But if a researcher was to do a health study using protected health information (PHI), the research use of that data wouldn't fall under HIPAA but would be regulated by the new privacy approach.

That approach would make a distinction between two types of research, Visscher says: Interventional research involving interactions between researchers and subjects; and informational research involving the use of existing health data or biospecimens.

In dealing with interventional research, Visscher says, studies would be reviewed under the Common Rule, with IRBs looking at privacy as one of many issues raised.

"It's the rule that IRBs are used to in the first place," she says. "We would assess risks and benefits, we would look at the privacy implications, we would see how people are protecting the confidentiality of the data – all the things we always do when we review a research study."

Informational research, on the other hand, raises many more complicated issues of data security and privacy protection that IRBs aren't well equipped to handle, Visscher says.

"We proposed a new oversight system for that type of research," she says. "This system would be very focused on how the data are protected, what computer systems are in place for protecting the data, how are you de-identifying data, how are you making sure that people don't attempt to re-identify people, what are your procedures for sharing data or linking data.

"And we felt like this new oversight would probably require a totally new review board that would be composed of people who have expertise in data security issues," Visscher says.

Under this system, organizations could be certified by the U.S. Department of Health and Human Services or another body to collect and analyze personally identifiable health information for clearly defined purposes, potentially from multiple sources, without individual consent.

"These organizations would show they have procedures in place to protect data and have a privacy officer and use state-of-the-art security techniques for encryption and sending data securely," Visscher says.

Large academic institutions could serve as these certified organizations, or an outside entity such as a private business could be created for that purpose, Visscher and Nass say.

Plan B – improved guidance

If Congress and HHS do not follow the IOM committee's main recommendation and continue to require that health research be conducted under the Privacy Rule, the committee included a wish list of guidance and other improvements it would like to see to help IRBs and researchers better cope with HIPAA requirements. Most would require HHS action:

— increasing knowledge about best practices in privacy protection using protected health information, showing how institutions are facilitating research while still protecting privacy.

"There should be a set of case examples that (IRBs) can look to for advice as to what decisions are really acceptable and even ought to be made under the HIPAA Privacy Rule," Nass says. "It would give them more confidence in feeling that they're doing the right thing."

— developing guidance clarifying how people can grant authorization for future use of their health data or biospecimens. The guidance would clear up concerns about whether a separate consent form is needed when a person enrolls in a trial and authorizes future uses of data or specimens.

"And what does 'future use' mean?" Visscher says. "Could it be a totally unspecified use as long as there's an IRB or privacy board reviewing it, or does it have to be related to what the original study was about? There are lots of issues

IRBs can take steps now to protect patient privacy

Liability protection, breach notification

Doubtless, few IRBs are holding their collective breaths waiting for a massive overhaul of privacy provisions in health research. And even the IOM Committee on Health Research and the Privacy of Health Information's less ambitious recommendations for HHS guidance on use of HIPAA may take a little while.

But there still are steps that IRBs can take right now to better protect patient privacy while facilitating research, says IOM committee member Wendy Visscher, PhD, director of the Office of Research Protection at RTI International in Research Triangle Park, NC.

She says that regardless of how privacy protection is regulated in the future, IRBs should be ensuring that they have expertise in data security issues on their boards.

"IRBs have expertise in human subjects protection and various research areas, but not so much in encryption and secure socket layers (SSL), statistical disclosure and what really constitutes an identifiable data file," Visscher says.

"What we do here (at RTI) is we have a data security expert on all three of our committees. They look at all the protocols in the agenda, strictly for data security issues. They ask all sorts of questions about different hardware that's being proposed to collect data or how we're storing the data or how it's going to be shared with someone else."

She suggests some sort of liability protection for IRB members in the event of a data breach, if they've done their job in good faith.

Visscher's other recommendations for IRBs include:

— creating a standard notification procedure to follow in case of a breach of data. At RTI, the breach notification procedure goes into effect when data is lost that is identifiable to the extent that it could be used for identity theft, she says. Participants receive a letter notifying them of the breach and are offered credit monitoring.

She says the last thing an IRB wants is to be creating such a procedure under the pressure of an actual breach. "Then, you're really scrambling and it needs to be timely for the benefit of the respondent."

— easing the process of releasing limited data sets to outside researchers. Visscher says many IRBs are requiring complicated data use agreements or business associate agreements.

"The guidance specifically says that business associate agreements are not required for research," she says. "A limited data set doesn't have any direct identifiers, so it shouldn't be so cumbersome to release that kind of data. But people were entering into these very long and extensive data use agreements and/or they were using business associate agreements. And it was becoming in some places so cumbersome that the researchers just gave up on it."

— helping to educate the public on the importance of access to health information in research. Visscher says IRBs can ask researchers about their plans for disseminating study results, which can help the public understand how health information is being used and its importance in improving care. ■

related to that that the committee thought there needed to be more guidance on, to help IRBs decide whether the consent form was adequate."

— creating guidance detailing under what circumstances a person's DNA should be considered protected health information.

"You think about DNA as being the most identifiable thing there is," Visscher says. "But if you have just a DNA sequence and you don't have any direct identifiers, unless you can link that sequence to another database that does have direct identifiers, well, then is it really identifiable?"

— reforming requirements for accounting for disclosures of PHI. "The committee thought the accounting of disclosures provision in HIPAA was very cumbersome and really almost impossible for covered entities to do correctly. And so they thought you should take research out from under that."

Asked about the IOM report, a spokesman for HHS's Office of Civil Rights, which enforces HIPAA, says the recommendations are being given "careful consideration…together with the viewpoints of other advisory bodies and stakeholders, as we move forward to ensure strong data protections without impeding quality research."

The statement from OCR also notes that work is under way on a trans-HHS Harmonization of Ethical and Legal Policies Related to Use of Human Specimens and Data in Research (HELPS). The HELPS project brings together agencies including OHRP, FDA, CDC and the NIH in an effort to create consistent policies on the research use of biospecimens and data.

Nass notes that the HELPS project, along with HIPAA provisions in the recently passed stimulus bill provide opportunities for addressing some of the recommendations in the IOM report.

"It actually is an opportunity to tweak HIPAA," she says. "It doesn't give us the opportunity for the broad new framework that we propose, but at least some changes could potentially be made in the rule at this point."

[Editor's note: To see the report "Beyond the HIPAA Privacy Rule: Enhancing Privacy, Improving Health Through Research", by the IOM Committee on Health Research and the Privacy of Health Information, visit the institute's Web site at www.iom.edu and click on the "Reports" tab.] ■

Ethical use of emergency exceptions to consent

New guidance pending to help IRBs, researchers

Is reluctance to permit exceptions from informed consent in emergency research (EICER) preventing important studies from moving forward?

A team of emergency research specialists is concerned that it might be, and is putting the finishing touches on new guidance designed to explain the ethical use of such exceptions. The guidance, developed by the National EMS Research Agenda Writing Group, is based on a 2007 EICER guideline consensus conference in Washington, D.C. that included investigators, sponsors and representatives from IRBs.

In recent years, use of the emergency exception has gotten widespread and sometimes critical public attention.

Michael Sayre, MD, associate professor of emergency medicine at Ohio State University in Columbus, and a co-investigator for the project, says that while EICER can be controversial, it provides an ethical way for researchers to conduct studies in situations where traditional informed consent may be impossible to obtain from unconscious or confused subjects.

He says that the initial goal of the guidance, which is expected to be published in its final form in late spring, was to provide a nuts-and-bolts guide to IRBs and researchers about how to conduct and review studies involving EICER. That goal was complicated by the varied opinions regarding the use of the exception.

"By the end of the meeting it was clear that we couldn't gain consensus around what exactly people should do," Sayre says. "But I don't think it's necessary that everybody does it exactly the same way. I think there ought to be variation depending on the relative risk of the study in question. And given the wide variety of different sorts of projects that might be undertaken, I think every IRB has to make a judgment about how they would approach the community consultation and public disclosure (requirements) for that particular study."

Important research

Sayre says the report does underline the importance of doing such research. The report notes that some IRBs have essentially refused to approve any research carried out using EICER.

"In my observation, for many IRBs, the temptation is to say, 'This is just too hard, so let's not do that,'" Sayre says. "There are too many people dying in our country from major injury or cardiac arrest who potentially could be saved if we just learned how to take care of them better."

Graham Nichol, MD, MPH, medical director of the University of Washington Clinical Trials Center in Seattle, says research into treatments for sudden cardiac arrest is a case in point.

He notes that while there are established treatments for sudden cardiac arrest such as CPR and defibrillation, they have low rates of success, pointing to the need for emergency research to find more promising approaches.

"We know that the average survival after out-of-hospital cardiac arrest in the United States is 8%," he says. "Some places are able to achieve much better outcomes, but overall, the existing treatments for out-of-hospital cardiac arrest are unsatisfactory, because 90% of people die."

Under EICER, a researcher may conduct a study in an emergency setting without obtaining individual prior informed consent from subjects.

IRBs may only permit studies to go forward under EICER rules if they involve life-threatening conditions, if existing treatments are unproven or unsatisfactory and in situations where subjects cannot give consent and a legally authorized representative cannot be contacted quickly enough.

The EICER rules in essence substitute a community consultation and public notification process for the traditional individual informed consent, Nichol says.

"It's not that there's no consent, it's that the community consents on behalf of the patients," he says.

Once a study is under way and subjects are enrolled while unable to give individual consent,

the researcher must inform them as soon as possible about their participation and give them the opportunity to withdraw.

One ethical issue raised by research conducted under EICER rules is that researchers must be able to access patient files to see if the study intervention harms the subjects. Sayre and Nichol say this holds true even if a subject withdraws from the study.

"People who discontinue from the study need to be followed to see what kind of outcome they have," Sayre says. "The FDA's position is you have to follow them, even if they say they don't want to participate any more.

"Clearly you can opt out of the continued risk of being in the study but the FDA feels strongly that if you allowed people to just opt out totally from any kind of further data collection, you could potentially introduce a pretty significant bias in measuring the outcome, and then maybe draw the wrong conclusion about whether the intervention worked or didn't work."

Nichol says this point is raised in the community consultation process.

"There's a description that in addition to giving you the intervention in the field, we're going to look at your records and check whether or not you were harmed by the intervention," he says.

Sayre says one question for IRBs is how much information should be given to researchers in those cases.

"You can follow somebody and tell if they're alive or dead without actually talking to them," he says. "Collecting that kind of information certainly wouldn't be intrusive. But if you wanted to sample their blood to see if they had some uncommon adverse effect, that must be viewed by most as unduly intrusive and not acceptable without consent."

In the end, Nichol says, the issues involved in EICER studies are similar to any other interventional study. What is the rationale for using this treatment? Do the risks outweigh the benefits? Have all reasonable steps been taken to ensure patient safety?

"Some members of the public are uncomfortable when they hear that someone is doing research without consent, but we all need to understand that when we do this special form of research in the emergency setting, the patient is not able to consent," Nichol says.

"I think the approach of getting the community to consent and having multiple committees check that we're doing the right thing before we start and check that we're continuing to do the right thing – and then notifying the patient and giving them an opportunity to opt out is actually the safest approach possible in this particular, narrow area of research."

[Editor's note: The final version of the EMS Research Agenda Writing Group's guidance on Exception from Consent in Emergency Research is due to be completed in late spring. To find the most recent version of this guidance, please visit www.researchagenda.org] ■

An EICER guide for IRBs

Community consultation is key

When looking at a study that would involve the use of the exception from informed consent for emergency research (EICER), IRBs first should consider whether the exception is necessary and appropriate, says **Graham Nichol**, MD, MPH, medical director of the University of Washington Clinical Trials Center in Seattle.

Nichol works with the Resuscitation Outcomes Consortium (ROC), a group of 10 clinical centers in the United States and Canada conducting collaborative clinical trials aimed at improving resuscitation outcomes.

He says an IRB reviewing the proposed use of EICER in a study must ask the following questions:

—Are the patients involved in a life-threatening situation?

—Are available treatments unproven or unsatisfactory?

—Is getting informed consent not feasible, because the patient is unconscious or confused?

—Is the research likely to directly benefit the patients?

—Can the research be done without the exception from consent?

If an IRB determines that an EICER is necessary, it then must consider the proposed community consultation and public notification process. This can take different forms, from community meetings to public notices in local news media to the telephone survey method employed by the ROC.

"The regulations encourage town hall meetings," Nichol says. "The sites participating in ROC tried to do that. The problem is you don't get a lot of people at town hall meetings. The sample you get isn't representative.

"Whereas if you do a random-digit dialing survey, you can ensure that you are getting a representative sample of young and old people, college graduates and high school graduates and people from different ethnic communities," he says. "To me, that is a much more balanced or representative approach to asking the community to consent to the research, which in essence is what we do when we do exception from consent research."

Michael Sayre, MD, associate professor of emergency medicine at Ohio State University in Columbus, says that when a conference was convened in 2007 to put together guidance on the use of EICER, it was difficult to gain consensus on a number of issues, including exactly what role the community consultation should play in an IRB's ultimate decision about a study.

"Was the purpose of it to let the community know, or to seek input about the study from the community?" he says. "We heard from different IRB people about their own interpretations of what this meant.

"Do you hold a vote – if there's 50.1% support, you go ahead? Or is it more consultative? Ultimately, it's the IRB's decision whether the study is ethical."

According to the proposed guidance, an EMS agency enrolling patients in a study is engaged in research and may be required to complete a Federalwide Assurance (FWA) for protection of human subjects. As part of that process, the agency must designate IRBs to review protocols and must train staff in research procedures.

Nichol says he doesn't believe EMS agencies would require any more or less training than would the nursing staff in an emergency department or intensive care unit. While he says EMTs sometimes don't have research experience, "they're used to rapidly identifying who's sick or who's not sick and initiating treatment as soon as possible. They understand that (research) is being done to improve the care that they provide to their patients, so they embrace that."

Regulations do not require that researchers give people in the community a chance to opt out of a study in advance, but FDA guidance recommends some mechanism for people to be able to register their opposition to potentially being included in a trial. That mechanism may take the form of an "opt-out bracelet" that can be worn or a wallet-sized card they can carry.

Once patients have been enrolled in a study while unable to give consent, the researcher must inform them as soon as possible about the study and give them a chance to withdraw if they wish, although researchers still can review their records to determine whether the study intervention caused harm.

When an IRB is encountering an EICER study for the first time, Sayre recommends checking with IRBs that have more experience in this type of research, to get ideas about how to handle particular issues or pitfalls to avoid.

Nichol says emergency research can raise new and challenging questions for IRBs, but it's worth the time and effort to answer them.

"Research in this arena can be difficult, but there

CNE/CME Objectives

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 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 letter of credit. When your evaluation is received, a letter of credit will be mailed to you.

COMING IN FUTURE MONTHS

- IRB learns a great deal from electronic conversion
- Formal IRB position helps both IRBs and graduate students
- Avoid IRB mission creep, following these tips
- Who's really the source of delay in getting clinical trials moving?

CNE/CME *questions*

17. An oversight IRB that consists of a research organization's IRB chairs could provide which of the following services?
    A. Serve as an appeals board
    B. Provide education to IRBs
    C. Be the IRB of record for institutional central office research projects
    D. All of the above

18. Which of the following would not be an ideal strategy for cutting IRB office, long-term costs?
    A. Move to an electronic system to cut paper costs and free up some staff time
    B. Lay off at least one IRB staff member and spread that person's workload among remaining staff
    C. Provide staff with flex time and a day of working at home to save on overhead costs
    D. Suggest Web-based education to cut back on conference travel time and expenses

19. The IOM Committee on Health Research and Privacy of Health Information recommended:
    A. Continuing to conduct research under the HIPAA Privacy Rule with no changes.
    B. Congress authorize HHS to remove health research from HIPAA and institute a new system of privacy protection for all health research.
    C. HHS revise the HIPAA Privacy Rule and improve its guidance on using HIPAA in health research.
    D. Both B and C

20. True or False: When a participant in a study conducted under the emergency exception from informed consent withdraws, researchers no longer can review the participant's file to see whether the intervention harmed him or her.

Answers: 17. D; 18. B; 19. D; 20. False.

are multiple layers of oversight," he says. "My experience has been that if investigators and IRBs and regulatory agencies focus on trying to improve care for patients, they'll find the appropriate balance between the need for consent, the recognition that consent is difficult if not impossible in this setting and the need to ensure both improvement in care over time and patient safety." ■