

IRB ADVISOR

Your Practical Guide To
Institutional Review
Board Management

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Mission Creep: Is it leading IRBs astray?

White paper makes case that IRBs have gone too far afield

Social behavioral scientists says IRB overreach is stifling research

Editor's Note: This month's issue of IRB Advisor contains a special report on the phenomenon known as "mission creep"—the charge that IRBs are inappropriately delving into fields of research that don't require their review. This story focuses on the Illinois White Paper, a project of social behavioral researchers at the University of Illinois. They recommend that IRBs withdraw from reviewing work in some disciplines in order to focus more fully on biomedical studies that more urgently need their oversight. Also, inside this issue are articles about how institutions should handle quality improvement projects that may or may not involve research and about how some IRBs have become overzealous in their pursuit of human subjects protection. To view the Illinois White Paper, visit <http://www.law.uiuc.edu/conferences/whitepaper/>.

The latest round in the ongoing debate between IRBs and social and behavioral researchers about the scope and effectiveness of IRB review has come in the form of a white paper, "Improving the System for Protecting Human Subjects: Counteracting IRB "Mission Creep," released late last year by the Center for Advanced Study at the University of Illinois at Urbana-Champaign.

The paper's authors, who represent a range of the social and behavioral sciences and many of whom have previously served on the university's institutional review board, say their effort isn't intended as an attack on IRBs. Instead, they say, they want to see IRBs freed up from activities that don't require their review so that they can focus on more pressing concerns of human subject protection.

"It was not a bunch of angry academics screaming, 'Academic freedom,'" says **Gregory A. Miller**, PhD, a clinical psychologist and professor at the university. "It was not a confrontational situation.

"We saw the pressures on IRBs — not only ours — growing. We saw universities running scared because the feds were shutting down

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places. We see the range of scholarly activity that might fall under an IRB, and we see IRBs expanding their reach, what we call mission creep, but applying rules that didn't seem to be that applicable."

The white paper explores those issues and makes a series of recommendations to IRBs and

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universities including one that could potentially be the most controversial: Removing IRBs entirely from some fields of study to which the authors believe IRB review is unsuited.

"In summary, expansive notions of university research and institutional commitments to the IRB reviewing *all* human research are untenable," the paper states. "The scope and purpose of IRB review must be clarified."

'More hassled than the baseline'

C.K. Gunsalus, JD, former executive secretary of the IRB at the university and currently an adjunct professor of law and special counsel to the institution, chaired the committee that wrote the Illinois White Paper. She was prompted to take up the issue after hearing more and more stories from researchers about examples of what she saw as overzealousness by IRBs.

"There's always going to be someone who says, 'Oh, I have to fill out this form, I have my important research to do; you're in my way.' There's a baseline," Gunsalus says. "But I was beginning to hear something different than what I have seen for more than 20 years. I began to perceive a theme of people feeling more hassled than the baseline."

Those concerns led to pulling together a group of academics to discuss the issue, and to convene a conference, inviting experts from both sides of the IRB board table. The resulting report identifies two separate but connected issues arising in IRB review:

• **Overemphasis on documentation issues**, even to the detriment of real ethical review. The authors note that the most frequently cited lapses in IRB audits by OHRP and the FDA are "poor or missing standard operating procedures" and "poor minute keeping."

"It's very easy to end up saying, 'Let's count some more beans,'" Gunsalus says. "You can count signatures on consent forms, but consent is a continuing process, not a signature. Somebody needs to say, 'Yes, we have pristine files, do we have ethical research?'"

• **Mission creep**, or the gradual insertion of IRB oversight into new areas of study, which the authors suggest they may be ill-equipped to regulate.

The paper suggests that this is the result of a number of factors, including poor definition by federal authorities as to what constitutes "research," "harm," or "risk." That leaves the

definition to IRBs, which may lack the expertise to know how to apply those terms to minimal-risk social and behavioral research. The IRBs also may over-regulate out of a knee-jerk fear of allowing research that may result in a government shut-down or a lawsuit, the authors say.

The resulting climate leads to incidents in which, for example, an IRB required an anthropologist to administer written consent forms to an illiterate tribe he is studying. Or journalism students were required to consider the potential risk to sources they interviewed for articles. Or an IRB wanted to review a proposal to analyze taped speeches by the late President Ronald Reagan that were stored at his presidential library because at the time of the proposal, he was still living.

The authors argue that beyond stifling some research, this system overloads the IRB, short-changing important work in protecting subjects of biomedical research. And they say it leads to a deterioration of confidence in the IRB by researchers, who may then seek to bypass it.

"I believe very, very strongly, that compliance systems require respect and buy-in from the regulated to function," Gunsalus says.

Not all agree

Those who work with IRBs, not surprisingly, disagree with some of the white paper's assertions, particularly its recommendation that areas such as oral history and journalism be removed from the purview of IRBs.

Jeffrey Cohen, PhD, president of HRP Associates Inc., located in New York City, is a consultant for IRBs. He discounts the argument that because many social-behavioral science activities are low risk, an IRB shouldn't have to review them.

"That's not all that IRBs look at or are responsible for," he says. "Risk is only one component. They also should be looking for respect for persons, which has nothing to do with risk. And they should look at justice, the exploitation of subject groups."

Cohen also believes that researchers can't be objective about the true risks of their work, and need someone to review it who can look at it more detachment.

"Now, that doesn't necessarily need to be a full board IRB review," he says. "It could be expedited review, it could be review for exemption. There's a lot of flexibility in the regulations

about how that review can take place, and a lot of it applies to minimal risk research."

But those involved with the white paper group say such a review can be accomplished without involving the IRB. **Edward M. Bruner**, PhD, a professor of anthropology at the University of Illinois who has done extensive ethnographic research, says his work could be more effectively addressed by a review panel within his own department, which would understand the complexities of informed consent in ethnography, and could apply his own professional association's code of ethics to his proposed study.

At the very least, he says, such departmental panels could serve as expert boards to advise the IRB in fields where it lacks the necessary expertise.

Marjorie Speers, PhD, executive director of the Association for the Accreditation of Human Research Protection Programs (AAHRPP), agrees with Cohen that all research involving human subjects needs to be under the IRB's authority.

"I don't agree with a blanket statement that there are no activities in the discipline of history or oral history or journalism that are human subjects research," she says. "It depends. Depending on the discipline, the vast majority of the activities might not be human subjects research, but there might be some that are."

But both Speers and Cohen agree with some of the other recommendations of the white paper including:

- **Conducting more empirical research** into IRB functions themselves, into the IRB decision-making process, about their workloads and their effectiveness in protecting human subjects.

The authors say it's ironic that this is an area of research that is under-explored. Miller says that's because the issues fall outside the realm of most researchers' areas of study. He and Cohen say another major factor is that there's little grant money available to pursue studies of the research process.

"I think the [National Science Foundation] and the [National Institutes of Health] should be funding this type of research," Cohen says. "I think professional organizations should probably be funding this type of research."

Cohen also would like to see more research into how participation in social and behavioral research affects subjects, particularly in the long term. "A lot of the possible harms that could come to subjects in social and behavioral research are not obvious," he says. "It's not like taking a drug and getting sick or having surgery and

USC booklet provides answers about human subjects research

The University of Southern California's Office for the Protection of Research Subjects provides tips on how to identify human research studies in its booklet, "Is Your Project Human Subjects Research? A Guide for Investigators." The booklet can be found on the university's web site at www.usc.edu in the research section. Here is an excerpt from the booklet, reprinted with permission:

Studies that are not human subjects research

Studies that fit any of these categories below do not need IRB review.

1. Data collection for internal departmental, school, or other university administrative purposes. Examples: teaching evaluations, customer service surveys.
2. Service surveys issued or completed by university personnel for the intent and purposes of improving services and programs of the university or for developing new services or programs for students, employees, or alumni, as long as the privacy of the subjects is protected, the confidentiality of individual responses are maintained, and survey participation is voluntary. This would include surveys by professional societies or university consortia.
3. Information-gathering interviews where questions focus on things, products, or policies rather than on people or their thoughts regarding themselves. Example: canvassing librarians about inter-library loan policies or rising journal costs.
4. Course-related activities designed specifically for educational or teaching purposes, where data is collected from and about human subjects as part of a class exercise or assignment but are not intended for use outside of the classroom. Example: instruction on research methods and techniques.

5. Biography or oral history research involving a living individual that is not generalizable beyond that individual.

6. Independent contract for procedures carried out for an external agency. Examples: personnel studies, cost-benefit analyses, customer satisfaction studies, biological sample processing (for a fee and not authorship or credit), public park usage, IT usage.

7. Research involving cadavers, autopsy material, or other bio-specimens from deceased individuals, do not require IRB review and approval.

8. Innovative therapies do not require IRB review and approval except when they involve "research" as defined by the above criteria.

9. Quality improvement projects are generally not considered research unless there is a clear intent to contribute to generalizable knowledge and use the data derived from the project to improve or alter the quality of care or the efficiency of an institutional practice.

10. Case histories which are published and/or presented at national or regional meetings are not considered research if the case is limited to a description of the clinical features and/or outcome of a single patient and do not contribute to generalizable knowledge.

11. Publicly available data to analyze public figures does not require IRB review.

12. Specimens and data sets (Secondary Data Analysis) that were not collected specifically for the currently proposed research study and the subjects are not identifiable do not require IRB review and approval. If the data set contains identifiers (either direct or link code numbers) but the investigator will not/does not have the code, then the study is not human subjects research. ■

dying. The effects of being in social and behavioral research are subtle and they could be delayed."

• **Seeking OHRP guidance** that more specifically addresses social-behavioral research.

"There are some inherent difficulties in the federal regulations, and so I think it's important for institutions to continue to have a dialogue with OHRP about what the concerns are and try to get OHRP to issue guidance," Speers says.

However, officials from OHRP declined comment on the white paper for this article, saying the response to the report was better left to IRBs.

Speers notes that the research community should communicate with the Secretary's Advisory Committee on Human Research Protections, whose Subcommittee on Federal Policy for the Protection of Human Subjects (Subpart A) is examining issues having a bearing on IRB review of social-behavioral research.

“Subpart A is where most of the challenges are for investigators and IRBs in reviewing behavioral and social science research,” Speers says. “It’s important to follow what that subcommittee is doing and to interact with that subcommittee so they hear loud and clear what the concerns are from the behavioral and social science community.”

- **Providing methodologically appropriate examples** for IRBs to use when reviewing social and behavioral research. The authors suggest that those examples could help clarify issues of “risk” and “harm” in non-biomedical settings.

- **Fostering development of “best practices”** in IRB operations, which could include such issues as potential appeal procedures, IRB membership, policy seminars and use of exemptions and waivers of consent.

Where do we go from here?

Miller and Gunsalus say they hope the white paper furthers the debate on the problems between IRBs and researchers, regardless of whether it results in all of the changes they have recommended.

Gunsalus says it’s particularly important considering the continuing efforts to bring even more research under the IRB’s responsibilities. “The next time there’s a scandal, and the next time there’s congressional interest, it will be all too easy to say we should make all human subjects research of whatever funding covered by federal regulations,” she says. “There’s going to come a time when these regulations are reopened. Let us be prepared so we can have a nuanced and informed discussion and really focus our energies on the places that have ethical implications rather than counting signatures.”

In the meantime, the paper does suggest that even without federal action on the issue, institutions can begin addressing it on their own, by looking at the degree of intensity they give research of different levels of risk and by using more flexible guidelines for research that is not federally funded.

Speers says AAHRPP tries to use the accreditation process to help educate IRBs not just about where they’re falling short of federal requirements, but also where they may be exceeding them and causing problems for researchers in the process. She says some IRBs may not be using mechanisms such as exemptions and expedited review as they should be.

“If we feel that they’re doing more than is required by the federal regulations — particularly if they have limited resources and they’re overburdened — and they’re not using all of these mechanisms that they have available, then we point that out,” Speers says.

All say that IRBs and faculty should work together to try to sort out their differences, and make the process work better.

Miller, who himself served on the University of Illinois’ IRB for several years, says researchers who are willing to delve into human subjects protection and even serve on a board themselves will have more knowledge and authority when they think an IRB is wrong. “If you served on an IRB, you might be an effective person to argue with them,” he says

Cohen believes that cooperation, rather than confrontation, is the key to getting IRBs to listen to researchers’ complaints.

“The approach should be, ‘How do we make the IRB work better? How do we make it more efficient, more flexible, more appropriate to the kind of research that we’re doing?’” he says. “If those were the arguments that faculty were making to those institutions, then they’d be more likely to get a positive response.” ■

Mission Creep: Is it leading IRBs astray?

Are marginal research activities clogging IRBs?

Expert discusses worst-case scenarios

Mission creep among IRB work occurs when research institutions and IRBs permit fear of missing something to rule their decisions, an expert says.

“It’s because of not understanding and also because the language is so general in the definitions of human subjects and research that so many things can be included or excluded depending on all the interpretations,” says **Susan L. Rose**, PhD, executive director of the office for the protection of research subjects at the University of Southern California in Los Angeles.

“The important thing is that people have overreacted out of fear of missing something,” Rose says.

IRBs across the country are finding their agendas clogged with reviews of projects that could marginally be considered research, Rose notes.

"First, IRBs are overworked, and then they add this stuff that should be subtracted," she says. "The work load is humongous."

The answer is better education and more clarity in the regulations. To this aim the University of Southern California has a booklet with guidelines that is available on the university's Web site at www.usc.edu, Rose says. (See sample excerpts from the booklet, p. 40.)

The booklet, titled "Is Your Project Human Subjects Research?" includes these definitions of research from the federal regulations 45CFR46:

- "A systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge."
- A human subject is "a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information."

The USC booklet underlines the words "about whom," because those two words are a very important concept in determining what is human subjects research, Rose says.

For instance, one IRB had not given serious consideration to these two words when it decided to review the proposal of a man who wanted to consult with architects and engineers to look at the soundness of buildings and their ability to withstand an earthquake, Rose says. The man had to seek IRB approval for a project that was not about human subjects, but was about buildings and the professional assessment of those buildings, she explains.

The person in charge of the building project was not able to interview the buildings, obviously, so there had to be people involved as experts, and just because there were people involved doesn't mean this was human subjects research, Rose says.

"Is the intent to test the architects to see if they are worthy of being architects, or is the intent to use their training and knowledge to identify the buildings with problems?" Rose says. It's not research just because you asked questions to establish a person's qualifications, Rose says. The architects' credentials were the criteria for establishing who they were, she says.

"For example, what if there's a physics experiment about Bunsen burner height of flame and/or radioactivity in flames, and you have physics students whom you have to ask whether they have been trained to work with Bunsen

burners or whether they're approved to work with radiation," Rose says. "These questions get the students over the threshold to be your experts, but it doesn't turn the focus of the research on them."

Another issue is the generalizability of research and what this means, she says.

"That has been broadened to mean that something you're doing becomes research if you publish it or even have a poster session at a meeting," Rose says. "Generalizable really means the intent to show it has validity beyond your particular experiment or condition or population."

Alternately, if a campus finds that certain buildings with certain types of ventilation are the ones in which students receive better grades, and so the university publishes this correlation, it doesn't mean that what is conveyed is generalizable and research, Rose offers as an example.

Likewise, quality improvement projects sometimes are misinterpreted, she says.

For example, a parks recreation entity wanted to find out if a particular park had good traffic, so staff questioned park users about their behavior in the park, focusing on what they ate and how they spent their money in the park, Rose explains.

This type of activity would not be considered human subjects research once an IRB focuses on the question of 'What is the point of the research?' Rose says.

In this example, the mission is to direct resources toward improving park usage, so it's a quality improvement project and not true research, she says.

It shouldn't be assumed that a project's findings are generalizable just because the findings are published or made public, Rose says.

"Generalizable means you're proposing or hoping or presuming the conditions of what you did are useful or valid in all similar situations," she explains. "That's why oral histories are not human subjects research a lot of times, because if you write about your next-door neighbor, you're not proposing that everybody is a next door neighbor."

Another step towards showing that something meets the definition of human subjects research is the concept of validating a process or equipment, Rose says.

"Quality improvement falls into this category," Rose says.

If an institution develops new software and then has staff or others validate the new software, the

research doesn't automatically become human subjects research just because humans are doing the validating, Rose explains.

Likewise, if someone asks curators at art galleries to report what kinds of exhibits draw in the public, this inquiry is not human subjects research, Rose says.

If the institution were to ask curators questions about their relationship to their employer, or what it is about their jobs that is horrible, then it would enter the realm of human subjects research, she notes.

Defining what is human subjects research and legitimately subject to IRB review will continue to be confusing, so it's important for IRBs and institutions to offer decision trees or guidelines for making this determination, Rose says.

The USC booklet offers guidance for investigators who have questions about their studies, and it provides examples of what types of projects are not human subjects research. "If someone goes through the decision tree and still doesn't know the answer or if there aren't clear answers, then we encourage the person to go to the IRB," Rose says. ■

Mission creep: Is it leading IRBs astray?

How much oversight for QI activities?

Expert offers suggestions for handling issue

The problem of how to handle quality improvement (QI) projects resulted in a research project that explored the intersection between research and quality improvement and ethical oversight.

"When you engage in data-based improvement activities, which are keeping track of what is going on and changing an improvement, you use a lot of methods that look very much like research," says **Mary Ann Baily**, PhD, Associate for Ethics and Health Policy at The Hastings Center in Garrison, NY. Baily made a poster presentation titled "The Role of IRBs in Ethical Oversight of Quality Improvement Activities," at the 2005 Annual Human Research Protection Programs Conference, sponsored by the Public Responsibility In Medicine & Research.

QI activities may have elements in common with research, so there is uncertainty about whether they require IRB review, Baily says.

IRBs and research institutions could establish policies for deciding which activities are QI and which are human subjects research, requiring IRB review. One first step to establishing these policies is to define quality improvement, Baily says. "Quality improvement is systematic data-guided activities, designed to bring about immediate positive changes in the delivery of health care in particular settings and through a wide variety of methods."

QI might look like a type of practical problem-solving, an evidence-based management style, and the application of a theory-driven science of how to bring about organizational change, she adds. On the other hand, research could be defined as a systematic investigation, including research development, testing, and evaluation, that is designed to contribute to or develop generalizable knowledge, Baily says.

Participation in research is optional, whereas participation in QI is not completely optional, she adds.

The Hastings Center, with a grant from the Agency for Healthcare Research & Quality, convened a multidisciplinary group of experts to compare and contrast three kinds of closely related activities: clinical adaptation and innovation, quality improvement, and research. The group reviewed and analyzed the accepted ethical requirements for research, taking note of to what extent they applied to QI, and drew conclusions about the type of ethical review and oversight that made conceptual sense for QI, she says.

The key conclusion is that QI requires ethical oversight, but the differences between QI activities and research justify different ethical requirements for QI, Baily says. "While QI is data-guided and has methods that are not unlike research, it fundamentally is an integral part of normal health care operations to make health care work," she says.

The current IRB process is not well-suited to the structure of QI activities, Baily adds. The problems with having IRBs review quality improvement projects is that the IRB process has high transactions costs and it does not fit the structure of many QI activities, Baily says. An institution that requires an IRB review of QI activities creates a disincentive for systematic monitoring and evaluation of change, Baily says.

Rather than sending QI activities to the IRB for review, it would be better to bring protection of human subjects of QI into the accountability system for clinical care, Baily notes. This can be

done through the development of a QI oversight system that is an integral part of ethical oversight of clinical practice and which matches management and supervision appropriately to the ethically relevant characteristics of the QI activity.

"There is more flexibility in the human subjects protection system than is sometimes recognized in the field, and OHRP encourages IRBs to specialize in the kinds of research they mostly see," Baily explains.

Consent requirements should be different for QI activities. For instance, a consent to inclusion in minimal risk/harm QI activities could be part of the consent to treatment, Baily says.

In establishing ethical oversight for QI activities, it is wise for an institution to provide guidance on ethical requirements and to establish an accountability structure with internal QI accountability categories, Baily says. ■

Tailoring IRB software to different sized institutions

Third Sky has options for small, large IRBs

The software demands of smaller IRBs and larger ones can be very different, and it's hard to meet everybody's needs with a single program. So Third Sky Inc. doesn't try.

Third Sky, an information technology company with offices in Boston, Dallas and San Francisco, produces two software products for IRBs — IRB WebKit, which is aimed at medium and large-sized IRB operations, and IRB+ for smaller IRBs. The company also has taken the first steps toward rolling out a third IRB product, aimed more at mid-sized users.

Reginald Lo, vice president-east of Third Sky, says IRB WebKit was the company's first IRB software product and evolved out of software that had been developed for use at Partners Healthcare in Boston.

IRB WebKit is a web-based, customizable system that allows IRBs to keep track of protocols, as well as IRB functions such as meeting agendas, minutes and continuing review notices. It allows researchers to submit protocols either online or in paper form, and lets IRBs track both processes easily, Lo says.

"For example, frequently the investigational brochure is a big folder and it only comes from the sponsor in a hard-copy form," he says. "So

we give the IRB administrator the ability to track whether that has come in. You can submit your protocol online, but you can also put it on hold in your inbox, waiting for the paper documents to arrive."

Ease of use, affordability

Lo says the software is easy for a non-technical user to master. That, and IRB WebKit's affordability, position it well against other IRB software marketed to larger IRBs, he says. "We're one of the cheapest within the market for the medium- and large-institution range."

The software allows IRBs to customize letters, minutes and database information to suit their own institutional needs.

Security measures are flexible and can be set to work with existing institutional usernames and passwords. There are different levels of access to the system depending on whether the user is a researcher, an IRB administrator or an IRB member.

When the WebKit is installed onsite, the company also provides training, which usually lasts two to six hours, depending on the level of user. Lo says Third Sky uses a train-the-trainer model for researchers, enabling IRB administrators to conduct researcher training as more researchers are brought into the new system.

He says his company advocates a relatively slow roll-out of the system to researchers, going department to department or by individual users' technical savvy instead of trying to bring everyone on board at once.

"There's quite a while where you're receiving online protocols as well as traditional paper [Microsoft] Word protocols," Lo says. "The IRB office doesn't want to get overwhelmed by suddenly having every researcher in the organization call up and ask 'How do I use the new system?' Hence, we recommend this sort of phased approach."

The licensing fee for the IRB WebKit is based on the number of IRB panels at an institution, rather than the number of users. "We use the number of IRB panels as a proxy for IRB size," Lo says. "It's easier than trying to remember how many users you have, especially when you're doing online submissions, where you could have thousands of researchers and that number changes every day."

The fee is \$8,000 for the first IRB panel, and \$5,000 for each subsequent panel. In addition to

the software fee, there is also a fee for professional services such as data conversion, setting up forms, training and onsite installation. Those fees usually run \$30,000 to \$50,000, Lo says.

The IRB at Baystate Medical Center, in Springfield, MA, switched over to IRB WebKit nearly a year ago from what IRB administrator **Maureen Nofall** described as an “antiquated [Microsoft] Access database that was on shaky ground.”

She and administrative director **Richard Engelman**, MD, say they’ve been pleased with the software, citing Third Sky’s attentiveness to their needs — and the price of the product.

“We had a number of demos of different products,” Engelman says. “Reg [Lo] gave the most reasonable presentation with the product that was the most reasonably priced. And not just by a few dollars — it was a quantum jump cheaper than anyone else.”

Nofall says the process of customizing the software for Baystate took only a short time, and she’s been impressed by the company’s response time for questions and other issues.

“Working with Reg and his team of folks has been absolutely wonderful,” she says. “If we’re in the middle of an issue, and we give him a call or send an e-mail, they respond within that day, and I find that very refreshing.”

Nofall says even the researchers using the software have had surprisingly few requests for changes to the online protocol submission process. “I thought for sure once we rolled it out they’d say, ‘Oh, this is very cumbersome, I don’t like it.’ But we took our forms that we had been using, and just transitioned them into the WebKit. The only difference for them is instead of typing onto an actual paper form, they’re now inputting the information into the WebKit.”

Option for small IRBs

For smaller IRB operations, Third Sky offers IRB+, which is an upgraded version of the IRB Navigator software previously marketed by West Beach Software.

Lo says that when West Beach made the decision to stop supporting IRB Navigator, the company asked Third Sky if it wanted to take over its remaining customers.

“We agreed to do it, but we also wanted to improve the technology, so we rewrote it for the Web, while retaining the same look and feel,” he says. Lo says about 75% of the remaining IRB

Navigator customers have been converted to the IRB+ product.

IRB+ allows an IRB to customize letters and reports to meet institutional needs, but is not as customizable as IRB WebKit, Lo says. “Much more of the structure is already set in stone for you,” he says. “So there are no consulting services associated with setting up.”

While it lacks some of the flexibility of the IRB WebKit, Lo says it offers an affordable option for small IRBs that want to have online capabilities. The annual fee for using IRB+ is \$3,000 for the first user and \$1,000 for each additional user. There are additional fees for services such as data conversion, Lo says. Training is conducted online, adding to the cost savings.

Diane Lesmeister, IRB coordinator at Olmsted Medical Center in Rochester, MN, says her institution purchased IRB+ last year to replace an Access database.

“We found a lot of studies that were missed, that we hadn’t corresponded with for progress reports,” Lesmeister says. “When they started out they had good intentions, but as the study lists grew, it got harder and harder to keep track and to run queries.”

She says IRB+ is a good fit for her IRB, which currently keeps track of 325 active studies.

“We’re not huge, but this is perfect for a small IRB like ours,” Lesmeister says. She says one important feature is the ability to export data from IRB+ into a Microsoft Excel spreadsheet, which she can then share with another institution’s IRB.

Lesmeister also praises Lo and his staff for their ability to work with her and turn around solutions to problems quickly.

The one added capability she’d like to see with IRB+ is the ability for principal investigators to be able to submit protocols online.

“What I’m doing right now is copying and pasting information, like a summary of the study into (IRB+),” she says.

Lesmeister soon will get her wish. Lo says Third Sky currently is beta-testing an online protocol submission module for the IRB+ software.

Third Sky plans to add yet another product to its IRB lineup, targeting mid-sized IRBs. Lo says the company recently made a deal with the University of Illinois at Chicago to license that institution’s Research Information Support and Communication (RiSC) software. He says Third Sky will upgrade the RiSC software much as it did with IRB Navigator, and incorporate online submissions as a new feature.

In each case, he says, the goal is to provide customers with greater functionality while preserving the software format they're accustomed to.

"We make sure each customer community has their own upgrade path," Lo says. "West Beach software customers did not have to learn a totally new system, i.e., IRB WebKit. What we gave them was something very similar to their old IRB Navigator product, except it was on the Web." ■

Regional consortium gives IRBs venue for information

St. Louis-area IRBs discuss common issues

Four times a year, staff and board members from IRBs around the St. Louis area get together to talk about the issues that concern them, in an effort to learn from each other and to jointly sponsor educational programs.

The St. Louis IRB Consortium, begun about four years ago by Washington University in St. Louis, includes a wide range of institutions, including large research universities and hospitals, and smaller, more specialized IRBs such as one from a local chiropractic college.

Members take turns hosting meetings, which revolve around set topics that the host institution or others have been struggling with, says **Sarah Fowler-Dixon Frankel**, PhD, education specialist for the human studies committee at Washington University.

"Conflict of interest, pros and cons of becoming accredited, vulnerable populations, quality assurance/quality improvement programs — whatever the IRB is grappling with at that time or things that are coming up that we think are interesting," Frankel says. "Speakers are usually free; we pull them from our own institutions."

The consortium recently was honored by the Health Improvement Institute with a 2005 Award for Excellence in Human Research Protection, Best Practice Division.

Michelle Reznicek, RN, MBA, JD, campus IRB compliance officer for behavioral and social science research at the University of Missouri-Columbia, says the consortium meetings have been invaluable for IRB members and staff at her institution — even considering the two-hour drive to St. Louis from her university's Columbia, MO, campus.

She notes that some of the resources provided by the consortium, including an OHRP discussion a few years ago that featured OHRP Director Bernard Schwetz, would normally require an expensive trip to a national conference.

"We try to attend as many events as we can and they're usually on the East Coast and the West Coast," Reznicek says. "Our boards are pretty big, and when you're trying to send a lot of members to keep them current on information, it's nice to have that educational opportunity that close to you."

"The St. Louis consortium has provided a venue right here in the Midwest to share experiences, to have access to government oversight agency members and also just to keep abreast of what is going on in the industry."

Inspired by Kansas City example

Frankel says her interest in a consortium was piqued when she was invited to Kansas City to attend a meeting of an IRB consortium there.

"They were drawing from quite a radius around Kansas City," she says. "There were different IRB professionals, committee members, chairs, and they were discussing some pretty timely topics."

"We liked the idea," Frankel says. "They actually invited us to join their consortium, but Kansas City is about four hours from here, a little far. So we thought it might be a nice idea to do the same thing here in St. Louis."

Washington University had previously conducted a joint town hall meeting on IRB issues with St. Louis University, the local Veterans' Administration and St. John's Mercy Medical Center in St. Louis. The group decided to use money left over from that event to begin a local IRB consortium.

Frankel says she invited IRBs from throughout the St. Louis area to join and attend meetings, which originally were rather informal, without a set topic for each meeting.

At first, it was slow going, she says. "At the first meeting, we only had one other institution that showed up. But we just went ahead and kept holding meetings. And the conclusion we came to was that in St. Louis, they wanted the meetings to be a little more formal. So now, we always have a scheduled speaker and topic, and we wrote a charter and developed a brochure."

She says that interest began to pick up after that.

Members now include the original institutions, the University of Missouri, Logan College of Chiropractic in nearby Chesterfield, MO, and Southern Illinois University Edwardsville, about a half-hour from St. Louis. Each member has an opportunity to host meetings at its own institution, on a topic of its choosing.

While the size and focus of the member institutions is quite varied, Frankel and Reznicek see that variety as an advantage. Frankel notes, for example, that the chiropractic college had done a lot of research with supplements, something her own institution didn't have much experience with.

"Other institutions might have other types of research or they might see more of it than we do," she says. "That's why whoever the host institution is gets to pick the topic. We can learn from each other."

Reznicek says that while the health sciences IRBs at the University of Missouri and Washington University are fairly comparable, her own institution has a higher volume of social-behavioral research.

"I've been able to share with them my experiences because theirs is significantly smaller than our behavioral and social science side," she says. "They've been able to share with us a lot of their medical because theirs is comparable to ours. It's been a good partnership. I think when you're sharing information in a compliance industry, it's all valuable."

Meetings are held quarterly, and usually begin at 4 p.m. They last about 90 minutes. "We've had meetings run as long as 6 p.m., but 1½ hours seems to be the best. If it does go more than two hours, it's because they happen to be getting into their discussion."

The host institution provides the venue and light refreshments. So far, the consortium has been able to operate without using up the seed money left over from the town hall event, Frankel says.

She says the University of Missouri hosted a meeting a few years ago, to show members its new paperless IRB software system. "They did come down and we did a presentation for them

so they could see what it was like," she says. And when her own institution faced accreditation, she could use other consortium members as a resource to help her know what to expect.

"That's what a consortium does for you — it saves you from reinventing the wheel in areas where somebody else has already brainstormed," Reznicek says. "You can tailor it to your own needs but you might not duplicate efforts."

Barbara Woodson, IRB administrator at Missouri Baptist Medical Center in St. Louis, has been attending consortium meetings for about a year and half.

She says that while she's been with the consortium only a short while, she's found the consortium useful for some purposes. However, in contrast with Frankel's observations, Woodson says she'd like to see some meetings less focused on a scheduled presentation and more on informal brainstorming about problems the member IRBs face. "It's great to have presentations and bring in speakers, but I'd like to see us get together over coffee and talk," she says.

Keeping it going

Frankel says it can be a challenge keeping an organization like the St. Louis IRB Consortium running. "Washington University has always been the point person," she says. "Even when things weren't that formalized and there wasn't much interest, we kept scheduling meetings and sending out notices."

Reznicek says a consortium needs to bring as many local players to the table as possible, to encourage wide participation. She says even small institutions should be encouraged to actively participate, including hosting their own meetings.

"Sometimes they don't realize that they have valuable information that even a large institution has encountered," Reznicek says.

"Anybody out there who really wants to set the standard should actively engage in and form a consortium," she says. "It will save you and allows you to have a more efficient review system, I can tell you that." ■

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CE/CME Objectives

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

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

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

13. Which of the following is not a recommendation of the Illinois White Paper titled "Improving the System for Protecting Human Subjects: Counteracting IRB Mission Creep"?
 - A. Entirely remove some areas of study from IRB review
 - B. Mandate IRB review for all research, regardless of source of funding
 - C. Foster development of best practices in IRB operations
 - D. Seek OHRP guidance more specifically geared toward social-behavioral research.
14. Which of the following is a good example of activities that should not be considered human subjects research for IRB purposes?
 - A. Data collection for internal departmental, school, or other university administrative purposes, such as teaching evaluations.
 - B. Service surveys issued or completed by university personnel for the intent and purposes of improving services and programs of the university.
 - C. Course-related activities designed specifically for educational or teaching purposes.
 - D. All of the above.
15. Which of the following is a good definition of quality improvement activities as they relate to the health care industry?
 - A. Systematic data-guided activities, designed to bring about immediate positive changes in the delivery of health care in particular settings and through a wide variety of methods.
 - B. A systematic investigation, including research development, testing, and evaluation.
 - C. An activity that is designed to contribute to or develop generalizable knowledge.
 - D. All of the above.
16. According to the University of Southern California's booklet, "Is Your Project Human Subjects Research? A Guide for Investigators," which of the following would be considered human subjects research?
 - A. Data collection for internal departmental, school, or other university administrative purposes
 - B. Information-gathering interviews where questions focus on things, products, or policies rather than on people or their thoughts regarding themselves.
 - C. Research involving cadavers, autopsy material, or other bio-specimens from deceased individuals
 - D. None of the above

Answers: 13. B; 14. D; 15. A; 16. D