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Your Practical Guide To Institutional Review Board Management

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Concerns about conduct are growing, but can research ethics be taught?

Even if they can, little academic training exists

For many years, institutions involved in training the nation's bioscience researchers have spent a great deal of time and money ensuring that their graduates function at the cutting edge of science and technology. But they've placed far less emphasis on ensuring that the same graduates are aware of the accompanying ethical, legal, and social implications of the work they do.

The high-profile cases of questionable research conduct occurring in recent years at some of these same institutions have led to questions about the need for formal ethics instruction for graduate students in the biosciences, say some instructors.

"We must teach our students the professional ethical rules that have been worked out by institutions and professional societies. They cannot hope to abide by rules they've never learned," advises **Roberta M. Berry**, JD, associate professor of public policy and director of the Law, Science, and Technology Program at the Georgia Institute of Technology in Atlanta.

"We must equip our students with ethical reasoning skills — just as we equip them with scientific reasoning skills — so they know how to apply the rules competently to the situations they will encounter in their professional lives. Students need to appreciate the implications of their work for others if they are to be ethically mature adults who take responsibility for their conduct and its consequences in their professional lives as they do in their personal lives."

Writing in a recent issue of the *American Journal of Bioethics*, Berry and colleague **Arri Eisen** from Atlanta-based Emory University examine the lack of formal ethics education for researchers in the biosciences and provide recommendations for future development of curricula.[1]

The vast majority of principal investigators in bioscience have received little or no formal training in responsible research conduct, Berry and Eisen point out.

Recent surveys of both professors and students reveal that although nearly 90% of graduate students from major research institutions reported

having supportive faculty members, fewer than half said these faculty provided a lot of help with regard to the details of good research practice. A fifth of the graduate students reported they got no help at all in this area.

As for the faculty, 99% of the 2,000 faculty members surveyed believed they and others in their positions should have collective responsibility for the professional conduct of their graduate students, yet only 27% felt that they followed through with this responsibility.

The are many explanations for the discrepancy between the perceived need for ethics training and the actual lack of it in the formal education process, Berry tells *IRB Advisor.*

"From the public perspective, bioscience research has been overshadowed over the last couple of years. On the one hand, by the larger research projects of physics and associated technologies — for example, nuclear weapons and nuclear power — and, on the other hand, by the more immediate and compelling ethical issues presented by the practice of medicine and by human subjects research," she explains. "Public scrutiny has grown only recently and in tandem with the enormous increase in public and private funding of bioscience research; its great successes — as for example, in mapping and sequencing the human genome — has increased worries about the ethical, legal, and social implications of bioscience, in particular, worries associated with genetic information and technologies and scandals about the conduct of bioscientific research."

Ethics by osmosis

From the researchers' perspective, there has been little prior public scrutiny of their work and many of them believed that ethical norms of their particular area or profession were being honored and passed down from veteran scientists to novice students without the need for explicit instruction, Berry notes.

"From the perspective of the bioscientist, the inside perspective, there has not been the sense of professional self-interest in developing and enforcing an explicit code of conduct to be used in instructing the next generation and in reassuring private clients as well as regulators that the profession's ethical house was in order," she continues. "Bioscience researchers are a diverse group of scientists without a singular professional identity, without individual clients, and, until fairly recently, without an immediate sense of public regulatory interest in their conduct. But the same pressures that have led to increased scrutiny from the outside — plus the globalization and expansion of research across diverse cultures — seem to be leading to increased interest from the inside in developing explicit instruction in research ethics."

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Editorial Questions

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But developing a formalized model of ethics instruction will not be simple.

Few experts in both bioethics and the basic sciences agree on just what exactly should be taught, how it should be taught — and how successful instruction can be evaluated, say Berry and others.

Different fields of science may have different perspectives on the same issues. And it's unclear whether traditional ethics faculty members or veteran scientists themselves are the appropriate instructors of ethics for bioscience graduate students.

"The crux of the matter is that not all disciplines deal with the same set of ethical issues. An animal researcher does not have to be concerned with whether the financial compensation for participation in research is coercive, for example," explains **Elisa Gordon**, PhD, assistant professor at the Neiswanger Institute for Bioethics and Health Policy at Loyola University of Chicago. Gordon and colleague Kayhan Parsi, PhD, wrote a commentary on ethics education in the same journal issue.[2]

"But what is less obvious," says Gordon, "is that even when disciplines share ethical issues, such as informed consent for human subjects, different disciplines have different approaches or even standards for obtaining consent."

For example, she notes, the Federal Policy for the Protection of Human Subjects or Common Rule has been undergoing revision under the supervision of the National Bioethics Advisory Commission (NBAC) and the Department of Health and Human Services. In 2001, NBAC proposed various efforts to strengthen the protection of humans participating in research, such as the requirement to obtain written consent. Many of these efforts, however, do not necessarily apply to all kinds of research, particularly ethnographic research, she argues.

In ethnographic research, written consent can undermine the rapport between an investigator and respondent that is essential to the research enterprise.

"Written consent and even oral consent can transform a trusting relationship into a hierarchical one. In addition, obtaining consent may not even be feasible when ethnographers conduct participant observation, that is, observing human events without disturbing their temporal processes and outcome," Gordon says. "Many scholars in the social sciences and humanities have responded to NBAC's suggested revisions about this problem. One of their suggestions is to include more social scientists on institutional IRBs in order to better address the variety of research methods and the ethical issues they generate."

Going beyond the basics

There are basic ethical concepts common to all areas of research, and pursuing a basic curriculum may be a worthwhile goal as long as efforts don't end there, she adds.

"A core curriculum that governs biological, chemical, and social science may be partly feasible if it addresses some of the broad issues relating to research ethics," Gordon says. "For instance, such a course may include a discussion of authoring publications, conflicts of interest, and plagiarism, among other topics. However, the course would be inherently limited by its attempt to be applicable to such a broad audience. It may be worthwhile to first identify what the general topics are, like the ones listed above, and then for individual disciplines to develop and adapt the topics for their own specific needs."

Berry agrees that it would be best for individual disciplines, with possible input from public policy scholars, sociologists, philosophers, and legal experts, to examine the ethical issues most relevant to their work. Then, in the future, representatives from the different basic science disciplines and different institutions may want to work together on a more uniform approach to ethics education.

"I think there will come a time when quality of research ethics education is associated with significant uniformity across institutions, with variation reflecting the distinctive character of different institutions as well as some pluralism with respect to the proper goals and means of ethics education," she says. "But, in the next several years, I think we'll learn best by proceeding as experimentalists, developing diverse hypotheses, testing them, and studying and comparing the results. This may well include multi-institutional collaboration in large-scale experiments aimed at developing models, and it certainly will involve drawing on the fine programs and supporting materials that have already been developed by a number of institutions and centers."

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2. Gordon EJ, Parsi KP. It's Alive! Giving birth to research ethics education. *Am J Bioethics* 2002; 2:65-66. ■

HIPAA challenges can be overcome, experts say

Should authorization form be a stand-alone?

Making changes under the Health Insurance Portability and Accountability Act (HIPAA) has not been easy for many research institutions and their IRBs. IRBs have considered several major decisions, including whether to combine the human subjects informed consent form with the HIPAA privacy authorization and whether to have the IRB handle HIPAA issues or create a separate privacy board.

Although it's still early in the implementation of such changes, HIPAA experts at two universities say that the transition to a HIPAA-compliant research institution can go smoothly if approached carefully and with attention to details.

It helps if the institution has had a history of paying close attention to privacy issues, says **Diane Clemens**, DC, CIP, HIPAA compliance manager of research at the Washington University School of Medicine in St. Louis.

"Our institution has always been quite conservative, and so many IRB policies already in place were more stringent than HIPAA requires," she says. "[HIPAA] compliance was mainly a matter of documenting what has always been the practice."

And that's where it pays to have a detail-oriented person in charge because the documentation is one of the major changes for IRBs and research institutions.

For example, at the University of Washington in Seattle the biggest impact of HIPAA has been the requirement that covered entities have to account for disclosures made without authorization, says **Helen McGough**, director of human subjects division.

"That's an enormous burden on researchers and entities," she says. "For example, the University of Washington Medical Center is requiring each researcher to keep a detailed record each time a case is accessed for research purposes, because now patients have a right to come to the hospital to see all disclosures made without authorization."

Each hospital or entity is handling the documentation issue in its own way, McGough says.

"At the University of Washington Medical Center the expectation is that researchers will pay for their own staff to keep accounting for those disclosures," she says. "We have set it up so that researchers download lists of disclosures they have made in a separate database, and any patient who comes to the hospital to request the data can go to a centralized database and receive a list of information."

The state of Washington had passed a bill that provided privacy protection years before HIPAA. The Uniform Health Information Act of 1996 forced the state's research institutions to educate investigators and clinicians about privacy and rules regarding using patient records for research, McGough says.

"So when HIPAA came down they were already thinking in those ways," she explains.

The institution educated IRB members, researchers, clinicians, and others about privacy regulations through its web site, newsletters, e-mail newsletters, and tutorials, McGough says.

"Since 1996, we've been developing a varied educational effort to encourage attention to issues of privacy and confidentiality," she adds.

Ongoing education needed

For most of the nation's research institutions, however, educating investigators, IRBs, staff, and especially health care gatekeepers to patient information about privacy rules will be one of the major challenges.

One group of investigators at Washington University has had trouble obtaining health information from hospitals that are not affiliated with the university because the hospitals' staff are afraid of releasing anything for research, Clemens notes.

Staff at hospitals where research is less common are unfamiliar with some of HIPAA's provisions for conducting research, and so they are overly cautious in working with investigators, she adds.

Probably the biggest decision that IRBs face is whether to combine the human subjects informed consent document with the HIPAA authorization, Clemens says.

"We talked with several institutions to find out how they were handling it and then talked with our investigators to learn their preference," she says. "The final decision was to combine the HIPAA authorization and the consent form, which means the IRB has to review the privacy information."

This was a critical decision because it meant that the IRB would have to take on a great deal of extra work, Clemens says.

"Several institutions had to go with separate

authorizations because they didn't have the staff to review a combined document," she adds. "We are fortunate to have the resources and support to carry out such a task."

The authorization template that was inserted in the consent form has to be tailored for each study, and on average it adds one-half to one page to the consent document, Clemens says.

For several months, Clemens and a staff of six reviewed all open and enrolling studies, assessing HIPAA compliance. Now the staff are looking at new submissions as well as taking on other duties, she says.

"One thing that caught us off guard was the role pharmaceutical sponsors would play in HIPAA," Clemens says.

"We were under the impression that since sponsors are not covered entities, they wouldn't have much involvement with HIPAA compliance," she says. "As it turned out, many sponsors had authorization language for investigators to include in the consent form."

That became a struggle between the IRB's template language and the pharmaceutical company language at a time when time was short to get everything completed, Clemens adds.

The HIPAA staff found it difficult to review the pharmaceutical company forms as quickly as they could review the template HIPAA forms, she notes.

So the IRB decided to ask investigators to include the IRB's HIPAA template in the consent form, and if the pharmaceutical company had its own authorization language, this could be included as a separate addendum with a disclaimer that the form was required by the sponsor and not reviewed by the IRB, Clemens says.

The IRB's role is to make certain that research protocols have integrated privacy in the process, and there are no additional IRB employees to handle the extra workload, she says.

"In addition, each hospital has its own privacy officer, and the privacy officer does monitoring, gives advice, and works very closely with the IRB on the educational effort and compliance effort," McGough explains. "We've been having meetings for years in preparation for this, and a large part of the effort was on education because we knew this would be a big change."

Another issue that IRBs will face is how to handle the privacy requirements when dealing with research that is conducted in a foreign country and/or is conducted by a foreign investigator, Clemens says.

"Our institution initially decided to treat all research the same, subject to regulations and authorization under HIPAA," she says. "The policies were written, and we failed to consider all the repercussions."

For example, the policies made survey studies and international research difficult to handle, Clemens explains. Now the institution is reviewing these policies and considering some changes, she adds.

Also, for retrospective studies that involve database searches, the IRB has combined the waiver of consent with the waiver of authorization form, and there are database custodians who are trained to know when to release protected health information (PHI), Clemens says.

"All approved studies receive an approval letter showing what the HIPAA compliance status is and what level of PHI may be accessed," she explains.

"Investigators provide this letter to the data custodians when requesting PHI, and the custodians then act as an audit system, tracking the flow of PHI," Clemens notes. "It seems to be working very well." ■

Special Report: Students and research protection

Should IRBs review public school studies?

In some cases, yes

(Editor's note: In this issue of IRB Advisor *is the second part of a special report on how IRBs are dealing with evolving policies on students and human subject research.)*

Monitoring student research isn't always a top priority for an IRB, and often the job may be partly handled by the student's department and graduate advisor. However, in the cases where the student research involves human subjects who are children, the issue becomes far more complicated.

Student researchers at Colorado State University in Fort Collins often need to conduct research in the fields of education, occupational therapy, and music therapy, using local public school students, says **Celia Walker**, MA, director of the regulatory compliance office.

The university's IRB shoulders a lot of

responsibility for these projects because there are no IRBs in the public schools, and for most of the people who approve the research at the school level, the concept of human subjects protection is foreign, she says.

"If the school's involvement meets the federal definition of engaged research, they technically should be reviewing it for IRB-type issues, but they don't know how to do that and they don't know what the regulations say," Walker explains. "So how can we get assurance from them that their students are being protected when they don't know what the regulations say?"

The ideal solution would be for the school district to have one person who is knowledgeable about IRBs and research ethics, who can make informed decisions about whether a school's students should be recruited for a particular investigation, she says.

"The more sensitive the research — such as drug and alcohol surveys — the more valuable that information is to the school and the greater the incentive for the school to approve it without thinking whether their students are adequately protected," Walker says. "That's where the pressure comes in to do passive consent."

Passive consent used to slide under the IRB radar screen, but it's no longer easy for investigators to bypass parents in obtaining informed consent, she adds.

For example, a proposed research project involves a nutrition curriculum with small children. As part of the project, they'll be fed new and interesting foods, Walker says.

There are some safety considerations that may not occur to the investigator or school staff, such as how to find out whether a particular student has food allergies, she says.

"The project staff will say, 'We'll just pull the kids' records and look at that,'" Walker adds. "Our IRB will say, 'You shouldn't have access to those records.'"

The problem is that it is too tempting for investigators to take the easy route to obtaining information because they recognize that teachers are overworked and don't have time to pull this information for the researchers, Walker explains.

The solution to this dilemma is for the IRB to require that investigators design a procedure that would have teachers scanning academic files to get the necessary information, she says.

"They had to receive verification from the local school district and had to have parental consent, also," Walker says.

Investigators were hesitant to call parents and explain the study and inquire about allergic reactions because they didn't want to scare parents away from having their children participate, she says.

Should I or shouldn't I?

So much of what occurs in educational research is questionable about whether it was intended to be subject to the human research regulations, Walker notes. "If you are a teacher, and you want to try a new math book for year, do you evaluate it and make your own decision, or do you tell parents that you are evaluating a new math book?"

Likewise, if a graduate student is writing a new math program that uses environmental measurements, and it's directed at third-graders, there isn't any way to decide whether this new program will work without testing it in third-graders, she says.

Whether an aspect of education is research depends on how one defines the type of research that is contributing to general knowledge, Walker says.

"Demonstration projects, evaluations, where do you draw the line?" she asks.

The American Institutes for Research in Washington, DC, involves students in state department of education studies of standardized tests, says **Douglas B. Gibson**, PhD, a senior research scientist and IRB administrator.

"We have done that for school districts in Pennsylvania, Ohio, South Carolina, and California," he says. "Some of this involves obtaining student records, and that's where people sometimes run into problems."

Such research must follow regulations under the Pupil Protection Rights Act, and this includes rules about sharing information with parents about instructional methods and obtaining informed consent from parents when there are sensitive medical or other questions being asked, Gibson explains.

For instance, the student survey questions that receive the most scrutiny are the ones that ask children about their psychological feelings and attitudes, he notes.

"If there are questions that are intrusive, or we feel like they might be psychologically damaging to the children, then we take those issues to the full IRB and don't do expedited reviews," Gibson adds. "We try to make sure there are sufficient protections in place, and we send protocols back to researchers over and over again until they're safe for students."

Occasionally, the IRB places so many burdens

on researchers that they'll back away from a project, Gibson says.

When research involves a large database of student information, the IRB makes certain the protocol doesn't require informed consent, because obtaining it would be impractical, he notes.

While IRBs may not be able to decide all of the gray areas, they can at least make certain that student and faculty researchers are well educated about human subjects protections and regulations.

"If you can do anything to improve human subjects protection it would be to get more people informed about human subjects issues," Gibson says. "Education drives the whole process."

At Towson (MD) University, members of the IRB routinely speak with graduate students about human subjects research in an effort to make them aware of ethical issues they may not have considered as they prepare to begin master's degree projects, says **Patricia M. Alt**, PhD, professor of health science and IRB chair for the Towson University IRB and the Maryland Department of Health and Mental Hygiene IRB in Baltimore.

"This university historically was a teachers' college, and we still have a lot of education research, psychology, mass communications, and other things, but it's the education research that is particularly tricky," she reports.

The problem is the rules were written for medical research with considerations involving the possibility of life-threatening medical interventions. Instead, the most common studies conducted by students would involve social science, behavioral, and other areas where a human subject could be harmed, but not physically, Alt explains.

"Our biggest interest is in making certain students learn something in the process about how to do research," she says. "We do require the faculty advisor to sign the form, and if the advisor signs it, it means the advisor has made certain the study is scientifically valid."

"We occasionally get complaints about things like grad students in education who are classroom teachers distributing surveys to their own students or to other students in the school," Alt says. "Once in a while, a parent will call up and complain that they were pushed to return the survey or whatever."

However, the extensive research education the graduate students are given has resulted in the process working quite well most of the time, she adds.

Another consideration IRBs should make in reviewing research protocols that will involve minors in schools involves studies that use passive consent, Walker says.

While an IRB may allow researchers to obtain passive consent, meaning that parents are asked to inform the school if they do not want their children to participate in a study, this sort of consent must be done carefully, she says.

"Our committee may put additional requirements on the process," Walker says.

For example, if the researcher doesn't present information about the study to parents in a timely fashion, then parents may not have enough time to make an informed decision, Walker states.

Also, investigators need to communicate the purpose of the study in a variety of ways to parents. For example, at a Native American boarding school, investigators wrote parents about the study and placed public service announcements (PSAs) on the radio in various communities, Walker recalls.

One IRB member asked the investigator what time the PSAs were aired, because often these are run when it's convenient to the radio stations and not necessarily at a time that the parents might be expected to hear them, she says.

"We expect investigators to use two to three ways of notifying parents that the study is on and how they can obtain information," Walker says. "It may be a creative and expensive process to reach the parents." ■

What about consent under emergency conditions?

Most IRBs can't answer that question

Except on the television drama "ER," it rarely occurs, even at medical universities and affiliated hospitals, but occasionally an IRB may encounter a case where an investigator desires to have informed consent waived in order to conduct emergency medical research.

When such a case arises, is your IRB prepared to handle it?

"Our policy is we take the waiver of informed consent on a case-by-case basis," says **John C. Smith**, MSW, CIM, IRB administrator at the Morehouse School of Medicine in Atlanta.

"For emergency medicine, it's our policy to allow the principal investigator to make that decision," he says.

For instance, if the investigator encounters a case where a particular patient's life is in jeopardy

unless an investigational intervention is made, the clinical investigator will take care of the patient and then, within 48 hours, inform the IRB of what has happened, Smith explains.

IRBs may not be ready to handle such cases because emergency medical research is so rare.

"It's been recognized that research in ER [emergency room] settings, and therefore advances in clinical care in those settings have fallen behind other areas of medicine because of the difficulty of getting consent, because people are often incapacitated," says **Daniel K. Nelson**, MS, CIP, director of human research ethics and an associate professor of social medicine and pediatrics at the University of North Carolina-Chapel Hill.

At UNC, there has not been any use of the waiver of consent for emergency medicine research, but the university's IRB is open to considering such a proposal if presented with one, he adds.

The Concord (NH) Hospital has had a few situations of emergency medical research, but it's very rare that the IRB ever waives informed consent, says **Lisa Rocheford**, MBA, CIM, education and research coordinator for the medical staff services and IRB manager.

"If there was a protocol that a physician wanted to use in the emergency department, we'd follow guidelines very closely," she says.

First, the clinician should know to inform the IRB even during an emergency situation of what is happening. Then the IRB would ask that family members be included and asked to give informed consent whenever possible. Finally, as soon as possible, the clinician should inform the patient of what took place.

IRBs can avoid after-the-fact emergency medical research conflicts by establishing criteria for how such a situation should be handled by clinical researchers, Smith suggests.

"There are situations where an expedited review could take place by an IRB administrator or an IRB chair or vice chair," he says. "But if in an emergency room situation, it's something that needs to be approved by the IRB prior to the procedure taking place."

For example, suppose an IRB administrator is called by a principal investigator (PI) and told that one of the PI's study subjects is in the emergency room, Smith says.

"And the PI wants the IRB's approval to administer something without getting the proper consent," he adds. "I don't believe we could act on that in that same day, because we'd just be reacting to a situation, and we wouldn't have time to process it and look at it."

Instead, the IRB could inform investigators that it is the IRB's policy to have investigators contact the IRB in advance when there are new and experimental procedures that might be used in an emergency medical research situation, Smith explains.

"This way, we can look at the risk-benefit ratio to see whether this procedure is worth doing and to see whether there might be some sort of subject coercion involved," he says. "When people are in shock, they especially need to be informed about what is going to be done to them."

Involve the patient advocate

In Georgia, a legal representative can make an informed consent decision for an incapacitated patient, so the IRB would ask researchers to also involve a patient advocate, because this impartial advocate can decide whether the person who is giving consent on the behalf of a loved one is indeed a legal representative who is entitled to sign an informed consent document, Smith adds.

There also is the question of whether emergency medical patients should be included in data collection studies without their informed consent.

The IRB at Concord Hospital had to take a look at this issue last year when the committee was presented with a proposal for research involvement in the Acute Decompensated Heart Failure National Registry (ADHERE), Rocheford reports.

The hospital will participate in the ADHERE registry as part of a quality initiative under its accreditation with the Joint Commission on Accreditation of Healthcare Organizations in Oakbrook Terrace, IL. The hospital's heart failure program nurses will do chart analysis and supply the data to the ADHERE registry, she says.

"ADHERE told our heart failure coordinators that if informed consent was required, the site couldn't participate in the study," Rocheford says.

"We took a look at this and the guides the IRB uses for the Food and Drug Administration, and we looked at protocols that were exempt from informed review or consent," she explains. "The study did seem to fit into the category of exemption because there was no deviation from the standard of care, no investigational products, and it was simply collecting data from patients who received care."

Since the people who participated in reviewing data for the study were the same people who were providing the patient care, there was no breach of confidentiality, Rocheford adds. "Everything

seemed to fit very nicely into the exempt category, and that's why it was allowed to go through as a quality improvement initiative and not as a clinical research trial." ■

SPOTLIGHT ON COMPLIANCE

Noncompliance calls for corrective actions policy

Develop policy before issues arise

By **J. Mark Waxman**, JD
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Inevitably, some investigators will not be compliant with the federal or state statutes and regulations, institutional rules, or IRB policies when conducting clinical research. While applicable state and federal laws have their own set of remedies, even criminal sanctions where appropriate, the IRB should develop its own corrective action and sanctions process.

The first step is development of the policy. That process would involve a series of defined steps, with the ultimate goal of having both the IRB and the institution adopt a Corrective Action and Sanctions Policy. The steps might be as follows:

1. The IRB would initiate the process by providing a notice that the IRB is developing such policies and seeking representatives from affected constituencies to participate in the policy development committee ("Committee") effort. The affected constituencies would include the medical staff, the principal investigator (PI) community, administration, and the IRB staff and membership, including its public member.

2. The Committee should develop a statement of the goals of corrective action and IRB sanctions. These goals would include the ability to take action to ensure patient protection, require the ethical conduct of research, educate PIs to prevent recurrences of inappropriate conduct, and protect the involved institution.

3. Standards should be developed as to when corrective action will be required. One standard, which uses the language applicable in a number of research contexts, is that such action is required when there has been more than a minimal failure to adhere to the applicable rules, requirements or policies in a way that has the potential to place either patients or the institution at risk. The actual risk involved need not have actually occurred to impose corrective action or sanctions.

4. An itemization of potential corrective or sanction actions should be developed. A listing of the potential actions should provide the flexibility to deal with a wide range of violations and indicate to PIs what steps might be necessary to cure violations. Actions listed would likely include a range from delay in approval or resubmission of a protocol, through suspension of a trial or preclusion of the ability of a PI to proceed with trials at the institution.

Another tool to be considered is the requirement of a proctor or clinical research overseer ("CRO") who would be responsible for providing assurance to the IRB that the PI involved has the necessary tools to conduct research at the institution. In listing the potential actions, and going so far as to develop standards for their use, PIs should be told that the emphasis in the first instance will be on required education and training. Corrective action is not designed to be punitive, but to assure the integrity, trustworthiness, and reliability of the research enterprise within the institution. PIs often do not really understand that one bad event can call all of that into very serious question.

5. A determination will be necessary with respect to who is responsible for corrective action and sanction decisions. The IRB will determine the specific action it will impose. It will typically hear from the PI involved before making a final decision. Where appropriate, input from others, such as the chief of the department, will be solicited.

There will be no appeal process from IRB decisions, as it is the responsible entity for research protection oversight for the institution and in the eyes of the federal government. Once the corrective action is determined, the PI and the responsible administrative officials should be notified. It should be the responsibility of the PI to complete the necessary corrective action, including ensuring any CRO reports are timely obtained and submitted.

The process will need to include input and consideration of other processes, which either may impact or could be implicated by corrective action or sanctions. There are two in particular:

First, the PI's or other members of the clinical research team may be employees of the institution.

It may be that a violation also constitutes grounds that implicate an employment counseling process. There should be a mechanism to cross-refer when it is appropriate to do so.

Second, the PI's or team members may be medical staff members and events, that came to the IRB's attention, also may fall into those professional conduct issues that would involve the formal peer review process. This can be a complex question. Certainly, consideration must be given to a peer review issue as clinical quality issues arise.

It is unfortunate that from time to time, corrective action — or even sanctions — will need to be implemented. To ensure their effects are as positive as possible and that the goals and reasons for their implementation are understood, IRB's should, in a fairly public way, develop an overall policy in this area. ■

Past abuses tar studies with prison populations

OHRP issues updated guidance

For years, inmates of a Philadelphia city jail, known as Holmesburg Prison, participated in medical experiments. From the mid-1950s to 1974, when medical testing was banned, research, ranging from dermatological treatments to the effects of mind-altering drugs, was conducted at the jail. Inmates were paid $2 to $3 per day while the jail collected hundreds of thousands of dollars in fees from the likes of Dow Chemical, Johnson & Johnson, and the U.S. military.

Three years ago, the office for Human Research Protections (OHRP) ordered the University of Texas Medical Branch at Galveston and the University of Miami to discontinue some of their research with prisoners. In their findings, OHRP listed problems with informed consent; the fact that some trials involved administration of an impermissibly risky drug; and possible conflicts of interest involving IRB members charged with approving protocols.

"Throughout the 1960s and the 1970s, there were disclosures of research involving prisoners in which it was clear that the prisoners were used because they were a convenient and captive population," **Michele Russell-Einhorn**, a director in the Global Pharmaceuticals and Life Sciences practice and the leader of the human subject protection advisory services group for PricewaterhouseCoopers, based in Washington, DC.

Such practices were unethical then. Today they would likely be considered illegal as the Department of Health and Human Services has strict guidelines for research involving prisoners.

In a guidance issued May 23, OHRP reminded IRBs about the special care that should be taken when reviewing protocols that use prisoners as research participants.

"It is important for IRBs to remember that research must fit into one of four very limited categories," says Russell-Einhorn. These categories include:

- study of possible causes, effects, and processes of incarceration and of criminal behavior;
- study of prisons as institutional structures or of prisoners as incarcerated persons;
- research on conditions affecting prisoners as a class;
- research on practices which could reasonably improve the health or well-being of the subjects.

In addition to the four categories, other special consideration by IRBs should include:

- possible advantage to participants;
- risks that are equal to those that might be experienced by nonprisoner participants;
- a fair selection process, including random selection of control subjects from the group of prisoners who meet the study selection criteria;
- information written in plain, understandable language;
- assurance that participation will have no impact on parole proceedings;
- adequate provision for follow-up care.

To ensure that prisoner concerns inform protocol design and the informed consent process, IRBs must have prisoner advocates on their boards.

"A prisoner advocate should not be the warden of the prison or an individual whose first loyalty is to the prison system," says Russell-Einhorn. "A prisoner advocate could be a public defender, a lawyer, a former prisoner, or a social worker from outside the prison."

Put simply, "the role of the prisoner advocate is to advocate on behalf of the prisoner," she says. "The prisoner advocate should be an individual who is familiar with and can understand the issues confronting people who are incarcerated, such as 1) limitations on their ability to communicate with people outside the prison; 2) limitations on amenities within the prison; 3) limitations on the food they eat and when they eat it; 4) how prisoners spend their time during the day."

When **Cindy Struckman-Johnson**, professor of

psychology at the University of South Dakota in Vermillion, conducted research in 1994 on sexual coercion involving women in Nebraska prisons, there was no prisoner advocate on her university's IRB. She took on that role, de facto, and designed her study with an eye on confidentiality and ensuring that inmates did not feel coerced into participating.

"Inmates are a captive population," Struckman-Johnson says. "Any information they give out could hurt the prison administration, which has retaliatory power, so they have to have special protections. I had to be careful about coercion and ensure that there would be no silent penalty for participating or not participating."

The issue of confidentiality had an impact on the informed consent process, she says. "Typically, when you get informed consent, you get a signature and that's your proof that they understand the study and that you have their permission. For that particular study, it was extremely important that inmates not have to put their names on anything linking them to the study."

Struckman-Johnson created a passive consent form, which stated that returning the questionnaire was their "voluntary agreement to be in the study."

The form also included an address and instructions that participants could contact her if they had additional questions or concerns. Some prison administrations didn't like that but, says Struckman-Johnson, "when I explained that I had an ethical obligation to respond to concerns I was allowed to do so."

Currently, her university IRB has a consultant who serves as the prison advocate when the need arises. "Her background is in prison research," Struckman-Johnson explains. "She has studied prisons her whole career, so she's very knowledgeable about the concerns of prisoners."

This year, Struckman-Johnson was called in to be the prisoner advocate on a study concerning sexual assault. The one flag for her was the investigators' proposal to collect names. She advised against it. "If confidentiality is lost, many penalties, some of them life-threatening, could result for inmates." ■

Institutions prepare for new accreditation program

The Partnership for Human Research Protection (PHRP) in Oakbrook Terrace, IL, recently announced the approval of final standards for a new accreditation program to safeguard the interests of human subjects participating in research efforts.

Ten organizations that have committed to PHRP accreditation have begun work on survey readiness evaluations. The first accreditation surveys are expected to begin this summer.

The PHRP released draft standards in December 2002 for testing and public comment. The final standards address organization responsibilities, institutional review board structure and operations, consideration of risks and benefits, and informed consent.

Organizations will use an on-line tool to evaluate their readiness for a survey and to initiate the accreditation process.

The accreditation process will involve a review of the evaluation results and supporting documentation, and an on-site survey, during which a team of PHRP surveyors — individuals experienced in biomedical research — will validate performance against the standards.

A partnership between the Joint Commission on Accreditation of Healthcare Organizations and the National Committee for Quality Assurance, the PHRP provides a national set of standards and a voluntary oversight process that creates a framework for ensuring that processes are in place to inform and protect volunteer human research subjects. ■

COMING IN FUTURE MONTHS

- Should IRB members be paid professionals?
- CORE program carries informed consent to next level
- Missouri University's IRB wins best-practice award
- A guide to selection research education materials

CE/CME objectives

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

- **establish** clinical trial programs using accepted ethical principles for human subject protection;
- **describe** the regulatory qualifications regarding human subject research;
- **comply** with the necessary educational requirements regarding informed consent and human subject research;
- **apply** the necessary safeguards for patient recruitment, follow-up, and reporting of findings for human subject research;
- **explain** the potential for conflict of financial interests involving human subject research;
- **discuss** reporting adverse events during research. ■

CE/CME *questions*

Physicians and nurses participate in this continuing medical education program by reading the article, 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 in order to receive a certificate of completion. When your evaluation is received, a certificate will be mailed to you.

1. One of the biggest impacts of HIPAA on IRBs and research is which of the following?
A. The requirement that covered entities have to account for disclosures made without authorization
B. The requirement that covered entities have to create a HIPAA compliance position
C. The requirement that covered entities have to obtain informed consent for all patients represented in research databases
D. All of the above

2. Passive consent is always appropriate for research involving public school students.
A. True
B. False

3. Research involving prisoners should fall into which of the following categories:
A. Study of possible causes, effects, and processes of incarceration and criminal behavior
B. Research on conditions affecting prisoners as a class
C. Research on practices that could reasonably improve the health or well-being of the subjects
D. All of the above

4. Corrective actions for noncompliance of IRB, institution, or federal regulations could include which of the following:
A. Delay in approval or resubmission of a protocol
B. Suspension of a trial
C. Suspension of a PI's ability to conduct trials at the institution
D. All of the above

Answers: 1-A; 2-B; 3-D; 4-D.