IRB ADVISOR

Your Practical Guide To Institutional Review Board Management

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IN THIS ISSUE

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Scientists say rules and pressures to produce lead to everyday misbehaviors

A new study reports that ethical lapses occur in daily work

A recent study has found that researchers acknowledge engaging in "normal misbehaviors" in their everyday research life, including abusing post-doctorate students, taking credit when it's not due, culling data based on experience, and shabby documentation.[1]

"One thing I thought was most interesting is the scientist who was saying, 'We labor under ridiculous rules, and we have to make a judgment: Do we follow this rule even though we think it's ridiculous?'" says **Raymond De Vries**, PhD, an associate professor in the bioethics program and in the department of medical education at the University of Michigan in Ann Arbor.

"Sometimes, not following the rule is to the more ethical thing to do," De Vries notes.

The scientists also complained about having too many rules to follow and the way sometimes IRBs in requiring informed consent could impede good research.[1]

One scientist gave this example of a senseless rule: Half of physicians in a department give a particular drug for headaches, and the other half give a different drug. Physicians decided to find out which drug works better.

But when they proposed doing a study to see which drug was better, the IRB required informed consent from all of the patients included in the study, even though they were patients who would be receiving one of the two headache medicines regardless of the research.[1]

De Vries and colleagues at the University of Minnesota were interested, generally, in the behavior of scientists and how it was related to the environments in which they work. There's always an interest in misconduct and bad apples, De Vries notes.

For example, within the past year, the international media was saturated with reports about South Korean Hwang Woo Suk's fabrication of data in his supposed pioneering work in stem cell research. Other reports of researchers fabricating data also have raised public ire, and condemnation from the research industry.

However, De Vries and other investigators were interested in what goes on below the public media radar screen.

"One of my colleagues, in particular, has been interested in stress in the workplace and how it affects people," De Vries says.

Investigators proposed holding focus groups with scientists to see what they consider their everyday problems in their work, he says.

"We came into the project with the idea that someone needed to pay more attention to the social environment of science, and we weren't going to settle for just looking at misconduct," De Vries says.

Investigators focused on everyday misconducts, as opposed to the big three ethical transgressions of falsification, fabrication, and plagiarism.

"We had a suspicion that there were more things going on than falsifying data and plagiarizing," De Vries says. "And in the focus groups, we discovered that yes, indeed, there were all sorts of things going on that scientists worry about."

Four areas of concern

They divided everyday problems into these four categories:[1]

1. The meaning of data: this includes dropping outlying results or observations based on a gut feeling that they are inaccurate, and it relates to sloppy record keeping.

2. Rules of science: this involves ignoring minor rules, such as materials-handling policies, and using funds from one project on a different project.

3. Life with colleagues: this includes exploitation of junior colleagues and making it more difficult for some scientists to conduct research based on social relationships with department heads.

4. Pressures of production in science: this involves a scientist changing the study's design, methodology, or results because of pressure from a funding source or the scientist's withholding of data and details in papers and proposals, as well as using another person's ideas without permission.

Scientists were asked to talk about what sort of things could get people in trouble in their line of work, he says. They responded that they were concerned about some of the smaller transgressions, such as not following rules outlined in a grant proposal and handling outliers in data, De Vries explains.

"Do you throw out an outlier if it makes the data stronger?" De Vries says. "Is that unethical, or is it just something you do to make the data stronger?"

The focus group scientists said the rules weren't clear, and they didn't know if they were cheating or not, De Vries adds.

Here were some of the other findings in the focus groups:[1]

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Editors: **Suzanne Koziatek** and **Melinda Young**.
Vice President/Group Publisher: **Brenda Mooney**, (404) 262-5403, (brenda.mooney@thomson.com).
Editorial Group Head: **Lee Landenberger**, (lee.landenberger@thomson.com).
Managing Editor: **Alison Allen**, (404) 262-5431, (alison.allen@thomson.com).

Editorial Questions

Questions or comments?
Call **Alison Allen** at (404) 262-5431.

• One prominent scientist would write lousy letters of recommendation for the research associates he liked so they would stay in his lab, and, alternately, he would write great letters for the people he wanted to get rid of.

• Research competition sometimes results in investigators taking credit away from colleagues.

• The pressure to produce and publish can lead to manipulation of the review system, funders exerting undue control over research, conflicts of interest that are unreported, idea theft and grant proposal theft, withholding of data, and ignoring teaching responsibilities.

• Professors sometimes use the work of graduate students and post-doctorate level people without their permission or giving them attribution.

• A company funding a study of radiation refuses to fund the study if a particular control group is included, so the professor is caught between the ethics of conducting the study the way he or she believes it should be done or becoming published, which can improve his or her chances of gaining tenure.

The focus group scientists discussed in detail the pressure under which they work, De Vries says. "We heard plenty of stories about how to succeed in science you need to get funding, and so there's pressure to keep up your funding and publication record," De Vries says.

So when a professor is pressured to use a research method that he or she doesn't believe is good science, what is the alternative? "She needs the funding to keep her lab going," De Vries says.

Scientists also discussed the politics of grant funding and stories about people stealing ideas.

"We heard about younger researchers presenting ideas at conferences and then hearing that a senior person at another institution wrote the idea in a grant and got it funded," De Vries says. "We heard stories of other people submitting a grant for a review, getting a bad score, and then somebody else got the same idea funded in the first round."

The latter story was mentioned so often in focus groups that it could be apocryphal and almost a myth, De Vries notes. "But it's an interesting myth," he adds. ■

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1. De Vries R, Anderson MS, Martinson BC. Normal misbehavior: scientists talk about the ethics of research. *JERHRE*. 2006:43-50.

Over regulating can put subjects at risk

Research ethicist offers ways to lessen that risk

In their zeal to protect research participants from undue risk, are IRBs actually making them more vulnerable, by causing frustrated researchers to circumvent the IRB system?

Research ethicist **Patricia Keith-Spiegel**, PhD, suggests that dynamic may be in place at some troubled research institutions. She worries that an IRB's overzealousness or uncooperative attitude could drive some research underground.

And she says there's even a model that explains this type of behavior: *organizational justice theory*, which predicts that employee (or in this case, researcher) misconduct will increase when a system is perceived to be unfair, arbitrary or biased.

But Keith-Spiegel suggests there are things IRBs can do to prevent such incidents, simply by changing the way they deal with researchers and making their processes more transparent.

"I think in some ways, if IRBs are amenable to it, it's a fairly simple fix," Keith-Spiegel says. "It doesn't require a lot of staff. I think IRBs would look at [the suggestions] and say, 'We could do that a little better,' and it might really pay off in ways that they don't even recognize."

Researchers get around IRBs

Keith-Spiegel, of Aptos, CA, is a consulting editor of the journal *Ethics and Behavior* and is past chair of the ethics committee of the American Psychological Association (APA). She says she became interested in the workings of IRBs when she began hearing anecdotally about social-behavioral researchers at various institutions who had found ways to avoid what they believed was onerous IRB oversight.

Examples of anecdotes were published last year in an article Keith-Spiegel wrote for the journal *Ethics and Behavior:*[1]

• An investigator considers her IRB unresponsive and arrogant, and so collects most of her research data as "regular educational assignments" carried out in her classroom or through required homework. When she finds data that interests her, she submits a protocol to the IRB requesting use of data already collected for non-research purposes.

• An investigator who has had several run-ins

with his IRB over issues he believes are picky and unnecessary, submits elaborate protocols he knows will bore readers, while distorting or omitting elements he believes the IRB might object to.

• An investigator who believes his IRB's consent requirements are too strict simply doesn't seek approval for his protocols. In doing so, he takes the chance that a publication based on a protocol never submitted to the IRB might be noticed.

Most of the incidents Keith-Spiegel learned about were among social-behavioral researchers, in part because she herself is a social-behavioralist. She says that the more extreme examples of IRB circumvention are probably less likely among biomedical researchers, where the risk to subjects and the potential for discovery may be greater.

Since the article was published, she's heard about even more examples of angry researchers circumventing their IRBs.

"There are people who have taken some really major risks, which rather surprised me," she says. "It seems like the more draconian the IRB is, especially when it's accompanied by arrogance, and perceived incompetence , those are the institutions that are really at risk for this phenomenon."

When Keith-Spiegel studied more about organizational justice theory, these incidents began to make "a sad sort of sense."

The theory is often used to study fairness and perceptions of fairness in the workplace, and how those perceptions affect employees. There are three facets to organizational justice:

• **Procedural justice:** appraising the process used to make decisions, whether they're seen as fair, consistent and accurate, and whether employees have a voice in decisions.

• **Interactional justice:** how people are treated by decision makers. Even when there's a negative decision, an employee is more likely to accept it if he or she feels respected and treated with care.

• **Informational justice:** full explanations of the decision-making process, so that an employee understand the basis for an unfavorable decision.

All of these facets play into negative perceptions that researchers have about IRBs, Keith-Spiegel says. In fact, she notes that when researchers were surveyed about what qualities they wanted to see in their own IRBs, qualities of organizational justice topped the listed, ranking even above protection of human subjects.[2]

"This was a huge national sample of federally funded investigators," she says of the survey, which was published this year in the new *Journal of Empirical Research on Human Research Ethics.* "Protecting research participants, although important, was No. 7 on the list. That's absolutely fascinating, how important this stuff is to researchers."

Keith-Spiegel says IRBs need to understand that for researchers, ability to conduct research is more than a career or money issue.

"It's about their self-concept, the research is really who they are," she says. "I think IRBs need to understand that that's why researchers may be so anxious and so obnoxious. Because to them, it's so critically important."

Dissatisfaction about the way an IRB operates can make an investigator more prone to excuse misconduct. Keith-Spiegel has conducted a study in which researchers read a vignette about an investigator who was turned down by an IRB, but with varying degrees of "fair" or "unfair" treatment. The investigator in the vignette then responded with differing types of scientific misconduct.

"Participants who felt the researcher had been treated unfairly were much more sympathetic to what he did," she says. "Even though they disagreed with what he did, there was tremendous empathy for his plight, in the situations where he was treated poorly."

Assessing attitudes about IRB

How can IRBs even know if researchers believe them to be unjust, let alone correct the impression?

Keith-Spiegel believes an IRB should take steps to see how it is viewed by its researchers. She and co-author Gerald B. Koocher, current president of the APA, have developed the Institutional Review Board Researcher Assessment Tool (IRB-RAT) that IRBs can use to determine how investigators perceive their IRB. The tool is available at www.ethicsresearch.com/forms.html.

"I think it would be really good for IRBs to take their temperature every so often," she says. "I've got maybe 40 or 50 universities using our IRB-RAT to see how the community feels about the job they're doing."

She also suggests that IRBs examine their processes to see areas where they could improve:

• **Transparency.** Keith-Spiegel says the procedure used by the IRB has to be stated clearly and widely disseminated so that every researcher understands what happens when a protocol is submitted.

"I think it really helps if the whole process is demystified — everybody knows when you hand it in, here's what happens first, here's what we do next. Instead of seeing the IRB as this mysterious group of people in there tearing things up."

• **Avoiding bias.** Keith-Spiegel says IRB members need to be alert to the possibility of bias in their decisions and those of other members. "It's so easy to be biased, especially if somebody is assigned the protocol to present to the rest of the group," she says.

"[IRB members] really have to watch out that they're really focusing on the protocol itself and not other extraneous factors. Whenever somebody finds themselves saying 'I think,' that's something you should look at."

• **Respect.** She says this factor is key to improving perceptions of researchers about their IRB. "This really seems to be the most important when it comes to the problems of people getting angry and then trying to circumvent the IRB," Keith-Spiegel says.

"It costs nothing to be pleasant and respectful, even in the face of an obnoxious researcher. I think sometimes IRBs think that to be respectful and pleasant is a sign of weakness, but it's really not."

• **Information.** She says researchers need to get a full explanation of an IRB's decision, particularly if it's unfavorable. Keith-Spiegel says one colleague told her that the colleague's IRB delivers bad news in a form letter with an X in a box marked "Disapproved."

"That's just absolutely unacceptable," Keith-Spiegel says.

She says that an IRB should take the time to write out an explanation when a protocol is disapproved, a practice that would also help weed out bias. "As you're writing out those decisions and the justifications for those decisions, if it doesn't look right, it probably isn't," she says. "I think sometimes biases can be picked up at that point."

• **Giving researchers a voice.** She says researchers whose protocols have been rejected should have the chance to address the IRB to make their objections known.

"Even if you get shot down again, if you felt like people listened to you, that's really helpful," she says.

"These are simple things that IRBs can do that will really increase the perception that the procedure is fair, that it lacks bias, that people making decisions are competent, that they're not just coming from their own idiosyncratic place," Keith-Spiegel says. "That's where you get so much resentment." ■

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1. Keith-Spiegel P, Koocher GP, "The IRB Paradox: Could the Protectors Also Encourage Deceit?" *Ethics and Behavior,* 2005;15(4), 339-349.

2. Keith-Spiegel P, Koocher GP, "What Scientists Want From Their Research Ethics Committee," *Journal of Empirical Research on Human Research Ethics,* March 2006; Vol. 1, No.1, 67-82.

Are you up on your state's research requirements?

You may be surprised by how it affects your IRB

As if it weren't enough keeping track of the intricacies of federal regulation of human subjects research, IRBs also must keep a sharp eye on state law, and the various areas where it puts additional or simply different demands on them.

In general, states don't wade into the federal regulation of research to add more restrictions on researchers and IRBs, says **John Isidor**, JD, chief executive officer of Schulman Associates IRB, an independent institutional review board in Cincinnati. Isidor is also on the editorial board of *IRB Advisor*.

Isidor, whose IRB often does work in different states, says that states such as California have added minor wrinkles to research review that savvy IRBs and investigators need to be aware of.

States often make laws regarding delivery of health care that can wind up affecting research, particularly in areas such as age of consent, privacy, and who can make decisions for adults who are unable to consent.

Like Isidor, **Paul Below**, a clinical research consultant in Burnsville, MN, has kept abreast of various state laws and their implications for researchers. When he speaks to research staff at various sites, he says, "My general impression is that a lot of the doctors are not aware of the nuances. Their expectation is that the local IRBs will know all this stuff, and if it's an issue they'll tell them. I find that that's not a great assumption."

Direct regulation of research

In 1979, the state of California adopted its own Experimental Subjects' Bill of Rights, and required

that any person participating in research be given a copy of the document. The listed rights, which include the right to know details about the study and its potential risks and benefits, closely mirror those existing in federal regulations, Isidor says. "It's a pretty benign requirement that just adds another form with little or no value, as far as I'm concerned, to the end of the consent document," he says.

Isidor says that after the 2001 death of Ellen Roche in an asthma study at Johns Hopkins University in Baltimore, lawmakers passed a bill requiring that all research conducted in the state be held to the same level of safeguards as those regulated by OHRP or the FDA.

"I think the [Maryland] attorney general and research participant advocates were the driving force behind this," Isidor says. "They had the legislature's attention because of this well-publicized tragedy at Hopkins."

In Massachusetts, the state's Department of Public Health regulates the use of investigational drugs, requiring investigators to have a special registration to dispense the drugs as controlled substances.

Isidor says that Massachusetts law also requires that when an external IRB not affiliated with a research institution approves an investigational new drug trial, it must visit the investigator's site once a year. Central IRBs operating in the state also have reporting requirements about the extent of their work, he says.

"I'm not sure what Massachusetts does, if anything, with this information, but it is in their administrative regulations," Isidor says.

Age of consent

More commonly, IRBs and investigators run into state requirements that were not directly targeted at research, but spill over from state regulation of health care in general, say Isidor and Below.

For example, rules regarding when and under what circumstances children can consent to health care procedures vary from state to state. While many states use the standard age of consent — 18 years old — in Alabama and Nebraska, the age is 19.

"When I talk to physicians in those states, they generally don't know that," Isidor says. "They just assume it's 18. If they're doing an adult research study and the FDA regulations reference state law in terms of determining the age [of consent], and they enroll an 18-year-old without parental consent, that would be a real problem."

On the other hand, in California, any child older than 7 who is participating in research must give assent, in addition to researchers obtaining parental consent, he says.

Below notes that in many states, minors still can consent to health care procedures and to participation in research if they meet different requirements: marrying, becoming pregnant, joining the military, becoming legally emancipated, or in some states, merely proving that they live independently of their parents or guardians.

Another area where state laws can affect research is in determining who has the right to make medical decisions for adults who cannot make such decisions themselves because they are incapacitated — for example, unconscious from an accident or because of decisional impairments such as mental illness or dementia.

Most states have mechanisms such as advance directives or health care proxies by which people can designate who will make those decisions for them, but in the absence of a document, many states also create a hierarchy of people close to the patient to determine who has the authority to make decisions.

Typically, that hierarchy will include a spouse, parents, adult siblings and adult children. In some states, even close friends or someone in a non-traditional relationship such as a gay or lesbian partner may make decisions for the potential research participant, Isidor says.

Often, this hierarchy only becomes an issue when there are disagreements among the relatives over a health care decision. Below says the most notable recent example of this type of disagreement came not in research, but in the Florida case of Terri Schiavo over a decision to withdraw life support. Schiavo's husband, Michael, eventually prevailed, gaining approval to withdraw life support over the objections of his wife's parents.

"The parents were fighting the spouse and the spouse won, and that was according to the hierarchy defined by Florida state law," Below says. "That would certainly be the case if it were a clinical research issue as well. If a spouse was willing to enroll a patient with Alzheimer's into a trial, but the adult children objected, then the wishes of the spouse would win out."

Isidor says the issue of surrogate decision-making is one that IRBs frequently find themselves grappling with.

"IRBs are concerned about it on a fairly ongo-

Resources to find state laws affecting IRBs

• **Books. Paul Below**, a clinical research consultant in Burnsville, MN, recommends a book published by Barnett International: "State by State Clinical Trial Requirements Reference Guide." Published in 2004, "it's in need of updating," Below says. But he finds it comprehensive in covering all of the areas of state law that pertain to research.

John Isidor, JD, chief executive officer of Schulman Associates IRB, an independent institutional review board in Cincinnati, has contributed a section on state law to the text *Institutional Review Board: Management and Function* published this year by Jones and Bartlett Publishers.

• **Web sites.** Below recommends that IRBs find the relevant areas of state law through citations in books and then visit the state government Web sites to examine those sections and ensure the laws haven't been amended.

On privacy issues, he also recommends a site founded by the Institute for Health Care Research and Policy at Georgetown University. The site, located at www.healthprivacy.org, includes a section on state laws.

ing basis and get opinions from institutional counsel or IRB counsel as to that issue," he says.

Other areas of state law that IRBs should review, according to Isidor and Below:

• **Privacy.** States may have slightly different, or even more stringent requirements about confidentiality of personal medical information than even the IRBs' usual bane, HIPAA; however, the differences are often minor. Washington state and California, for example, require that a privacy authorization include an expiration date, Isidor says. Some states require a certain type of font on the authorization document.

"Under HIPAA regulations, you can incorporate both the HIPAA authorization and the consent authorization with one signature," he says. "In California, it requires two separate signatures on separate pages."

• **Genetic testing.** Isidor says some states have specific laws related to informed consent and genetic research, including requiring the use of a specific form when genetic testing is conducted. In some states, the subject has the right to be informed of the results of any genetic testing.

• **Referral fees and gifts to doctors.** Although both practices are in decline, it's worth learning about any particular state laws that may prohibit fees for referring patients for research or limit gifts from sponsors of studies.

Isidor notes that with the advent of stricter privacy laws, referrals fees are less of an issue these days. "HIPAA has made people more sensitive that they shouldn't be referring patients, particularly referring [protected health information] for compensation or other reasons."

Below says there are a number of useful resources for learning about state laws that apply to IRBs (**see box, left**).

He says IRBs should use those resources to find out where in their own state code the relevant laws are found. IRBs should check the citations themselves, to be sure that no new legislation has been passed that may affect them.

State court decisions can create common law that affects IRBs as well, Isidor says. ■

More older women avoid research participation

But, once they've participated, they'd do it again

As IRBs work to ensure that women are fairly represented in clinical research, results from a new survey provide a disquieting message: More older women are uninterested in research and don't believe in participating.

The survey, released by the Society for Women's Health Research, a Washington, DC, advocacy group, also had some good news for the research community. More than 60% of older women who had previously participated in a medical study would be willing to do so again.

But getting them to agree to that first-time participation in a study is the key, says **Sherry Marts**, PhD, vice president for scientific affairs for the society.

In the study, 1,014 U.S. women age 50 and older were surveyed in April and asked about their attitudes regarding research. Their answers were compared to a similar survey conducted for the society among 1,017 women in 2003. A little more than 10% of respondents reported in 2006 that they had previously participated in a medical research study, down from nearly 12% in 2003.

Of the 2006 group who had been in a study before, 61.6% would be willing to do it again.

When asked what might make women hesitate to participate in a study, the most frequently chosen response was: "Just not interested in it/don't believe in it." In 2006, 15.9% of respondents chose that answer, compared to only 9.1% in 2003.

The second most common answer was "Too risky/dangerous/side effects," with 15.8% of respondents choosing this answer, up from 14.9% in 2003.

Why the large increase in disinterest in research? Marts says she thinks it's not so much a response to particular concerns about clinical research, as it is a general distrust of science that has taken hold in recent years.

Reports about the removal of drugs such as Vioxx from the market after patient deaths, controversy over stem cell research and the Plan B emergency contraceptive, even debates over global warming can lead to an environment in which people don't believe that research make a difference, she says.

Marts says the current climate in Washington these days is almost anti-science, and she believes that attitude trickles down the public at large.

"Science and medicine are things that people think of as hard — 'It's difficult, I didn't like it in school, I just don't even want to think about it anymore,'" she says.

"You couple that with the kind of publicity that the Vioxx situation has gotten — you couple it with the Plan B situation where disinformation about how the medication works has been the basis for objecting to having it approved. I just think there is this generalized, anti-research atmosphere that we're trying to function in, those of us who are research advocates and researchers, that just makes this doubly challenging," Marts says.

She notes that coverage of the Women's Health Initiative is informative in seeing why women might be discouraged from even entering a study. The long-term national health study focuses on preventing heart disease, cancer and fractures in post-menopausal women.

Recent results showed from the study showed that taking calcium supplements led to improved bone density, but to a less-than-expected decrease in bone fractures. Other recent results from the study showed that a lower total fat intake did not provide expected preventative benefits against breast cancer, colorectal cancer, heart disease or stroke.

Marts says that in each case, results were complex and nuanced, but the general public message that got out was not.

Exclusion issues

In the past, she says, her organization has had to convince researchers that it's important to focus on women as research subjects — that their biology is different from that of men, and so drugs and other interventions work differently in the female body.

Marts says she's seen improvement in that area. "There's a truism in the not-for-profit world that people don't volunteer it they don't feel asked," she says. "Part of our campaign was to make the 'ask.' Now what we're up against is not so much the ask — I think women do feel asked. I think it's 'What good is it going to do anyway?'"

While IRBs may not be able to do much to improve women's public perception of research, Marts, who herself has previously managed an IRB, says there are issues raised by the survey that IRBs can address as they review studies.

Two of the reasons chosen by respondents regarding reluctance to participate in research: "Health problems/not healthy enough" (9.9% in 2006, up from 8.3% in 2003) and "Age/too old" (9.4% in 2006, up from 6.6% in 2003) go directly to issues of how studies include or exclude potential participants.

Marts notes that it's harder to design studies around people with existing health problems, who may be taking a number of concomitant medications, but that such studies would more accurately reflect a drug's use in the real world.

Likewise, approving a study for cardiovascular treatment that sets a cutoff age of 65 would miss many women, who tend to develop cardiovascular disease later in life than men, Marts says.

She says there's current debate in the research community as to whether separate studies should be conducted of a drug's effects in older patients, which could lead to interesting questions about their use in women. "Does a drug behave differently pre- or post-menopause?" she asks. "They don't ask that question."

IRBs can ensure that the informed consent process is as easy to understand as possible, and doesn't scare away potential recruits.

And Marts says IRBs can continue to do look at local issues that may prevent women from being able to participate in a study. Examples of this may include lack of child care or concerns about personal safety at the research site.

"How far away is the parking lot? How safe is it to get to the clinic at night? We've had folks who've simply had an escort to walk women to and from the parking lot," Marts says.

The Society for Women's Health Research created a web site several years ago to help encourage women to participate in research as part of a campaign called "Some Things Only a Woman Can Do."

Marts says her group plans to update information on the site, www.womancando.org, which includes focus-group tested descriptions of clinical studies that can be used as text in informed consent documents.

There are also brochures and information kits in English, Spanish and a large-print edition that can be distributed to women.

Marts says one of the society's goals is to let women know more about clinical studies before they're ever diagnosed with a disease.

"We felt that even if getting the brochure didn't immediately lead them to participate in the study, at some point down the road it might be useful for them to already have this in the back of their head," she says.

She notes that work with focus groups revealed that many members didn't realize that they could participate in studies even if they weren't sick.

"They were surprised to learn about epidemiological studies or observational studies or prevention studies," she says. "It was really rewarding doing the focus groups because the women were hungry for the information." ■

HIPAA regs require firm policies, documentation

Train everyone in a health care system

IRBs and research organizations continue to iron out privacy policies and details 10 years after a law was passed to require health care organizations to adhere to federal privacy rules under the Health Insurance Portability & Accountability Act (HIPAA) of 1996.

For some institutions, it's worked best to have a separate privacy committee and a separate privacy document for subjects to sign. For others, the IRB and the research informed consent form serve a dual purpose.

As IRBs continue to look for ways to improve their HIPAA compliance, two experts offer a look at a best practice model, which includes strict standards on documentation, waivers of authorization, and other issues.

"Everyone was concerned about HIPAA when it first came out, and researchers are still concerned because there are extra steps they have to go through, and everyone is learning to live with that," says **Lori Coleman**, MBA, division ethics and compliance officer and HIPAA privacy official in two divisions of the Hospital Corporation of America (HCA) in Denver.

"Hospitals have always been in the business of protecting patients' privacy, so we made a set of rules to tweak our policies and procedures to cover the HIPAA mandate," says **Linda Mullins**, ethics and compliance officer at Sunrise Hospital and Medical Center in Las Vegas. Sunrise is part of the HCA health system.

Some of the changes that occurred post-HIPAA included increased audits, better patient education, and waivers required of investigators, they say.

"We made sure we were conducting regular audits and addressing any issues we found that violated HIPAA rules," Coleman says

After HIPAA, patients were savvier about how their private health information was used, and nurses and other staff had to begin having conversations about privacy, Coleman says.

"For principal investigators, what has changed is when they are required to get a waiver of authorization from either the IRB or a privacy board versus when they can automatically gather that information," Coleman says.

"Before HIPAA, we were gathering statistics and those sorts of things, but we didn't see those as research," Coleman says. "But now HIPAA says that if it involves patient information, it is research, except if it's for performance purposes within the hospital and it's considered quality improvement and is not subject to HIPAA."

Any time a researcher plans to use patient data for the purposes of publishing it as research, it's considered research and is governed by an IRB or privacy board, Coleman adds.

Even pre-HIPAA, patients signed a release about information in medical files so the information could be used for research, Mullins notes.

Now, research informed consent and HIPAA authorization to release information has been combined, which is different from what happens with non-research patients, who sign separate consent and authorization forms, Mullins says.

Here are HCA's best practices and policies and procedures regarding HIPAA and privacy:

1. Define HIPAA elements.

Research purposes are included on the HIPAA list of private health information uses and disclosures that must be tracked and documented. The rule specifically states, "Research purposes where a waiver of authorization was provided by the Institutional Review Board or preparatory reviews for research purposes."

This means that to use protected health information, an investigator must seek a waiver by an IRB or a privacy board.

"We use our IRB as our privacy board," Coleman says.

The waiver requires that the research involves no more than minimal risk for privacy of the individual, that the research could not be practically conducted without the waiver, and that the research could not be practically conducted without access to the protected health information, Coleman explains.

The IRB rarely approves waiver of authorization for research purposes because most of the time it is practical to get the patient's authorization, Coleman says.

"We try to give de-identified information as much as possible, and that eliminates the need for accounting of disclosure," Coleman says. "You can de-identify if you remove 18 elements."

2. Write policy about patient privacy and accounting of disclosures.

HCA has a 13-page policy about patient privacy and accounting of disclosures. The policy provides details about every type of disclosure, including waiver of authorization for research.

3. Enact rules about sharing information and educate staff.

"We have the expectation that anything with electronic information has an extra layer of security," Mullins says. "If it's sent outside our network, it has to be encrypted, and we shred all paper documents that have any type of protected health information on those documents."

There should be security for all laptops that connect to the network, Mullins adds.

"Our patient information is stored on our network, so the physician or the user of the laptop would have to log in, and our network is protected by a firewall," she explains.

The policy requires sponsors to be compliant with HIPAA privacy and security standards, as well, Mullins says.

The health care system has had to educate everyone who handles private health information, including everyone from infectious disease nurses to risk management department to the emergency room department, Coleman says.

"All of those areas have to be aware of what needs to be accounted for so hospitals can have those departments enter information themselves," Coleman says.

"We required all 3,000-plus employees and agency personnel to train on our HIPAA privacy information," Mullins says. "Everyone is required to learn our policies."

Mullins also led educational classes for physicians to explain how the privacy rule worked and what was expected of physicians, and now the same training is included in orientation and annual review curriculum. ■

CIP certification is taking off among IRB staff

Job listings often include CIP as a qualification

Nearly 800 people have worked to earn a certified IRB professional (CIP) designation in the six years since the first CIP exam was given.

The certification program's success has led to increasing numbers of job postings for IRB professionals who have or will soon achieve the CIP designation, says **Susan J. Delano**, CIP, deputy managing director for the Research Foundation for Mental Hygiene Inc. in Menands, NY. Delano has spoken at national IRB and research conferences about the CIP program.

"One thing that helped CIP launch successfully was the large number of people, who were well established in their IRB careers, saw the need for this," Delano says. "Even though it wouldn't benefit them personally, they took on the exam as a show of support for the field."

Now, the CIP designation is used as a means to gain employment or a promotion within an organization, Delano says.

There are two other reasons the program, which is sponsored by the Council for Certification of IRB Professionals (CCIP), is a success. For one, the program was developed by Public Responsibility in Medicine & Research (PRIM&R) and the Applied Research Ethics National Association (ARENA); and, two, the timing was right, Delano explains.

In recent years there has been a lot of focus on developing IRBs and making them more professional, Delano says.

"CIP was giving credibility and importance to the role of IRB administrators as a key component to strengthening human protection," Delano says.

"Independent IRBs have been a strong participant in this program, and a large number have required their staff to become CIP certified," Delano says. "My perception is that they see that as a way they can demonstrate to a broader community the professionalism and standards within their organization."

Based on a demographic report of the first 700 people who achieved a CIP designation, the following information is known, Delano says:

- 40% hold a bachelor's degree, 25% have master's degrees, and 17% report having doctorates.
- More than half had five or more years of experience, and 20% had more than 10 years of experience.
- Nearly 40% reported being employed by an academic medical center, and 15% were employed by an individual IRB. The remainder reported employment in a variety of institutions, including community hospitals, HMOs, industry, research institutions, and non-medical institutions.
- Three quarters of those certified were ages 30 years and older, and more than half were 40 years and older.
- Most of the people certified are women.

To be eligible to take the CIP examination, an IRB professional must meet these requirements:

- must have a bachelor's degree, plus two years of relevant IRB experience within the past seven years, or have four years of relevant IRB experience within the past 10 years;
- complete and file an application for the certification examination for IRB professionals;
- pay the required fee.

Relevant experience refers to hands-on IRB management duties and only applies to IRB members or chairs who handle regulatory compliance, IRB correspondence, documentation, IRB office management, and training, Delano says.

"We recommend people look at the regulations and guidances and national best practices," Delano says. Local policies and procedures and state laws are not a part of the exam, so it's important for CIP candidates to know the difference between what's required federally and what's required locally, she adds.

The CIP exam has 250 questions, and it's scheduled twice a year with a two-week testing window, Delano says. The test takes about four hours, and it costs $335 to $435, depending on ARENA membership.

Starting this year, the exam is offered through computerized testing, although some paper and pencil testing will be available based on individual circumstances.

More than 700 cities will host the CIP exam this year, making it cheaper and easier for people to find a test site, Delano says.

Those who have a CIP must recertify every three years, but for the first recertification they are permitted to recertify through continuing education credits. The next time they are required to take the exam again, Delano says.

The exam is kept current and thorough by unpaid volunteers on the certification council, and it's produced by the Professional Testing Corp. of New York, NY, Delano notes.

Each year the council holds an item review session with CIPs in different parts of the country, and together they go over the questions on the exam, Delano says.

"It's a two-day process to review each of those questions and make sure it's a question that should be asked and to make sure the question is clear, the answer is correct," Delano explains.

The council also makes sure the questions are pertinent to the required body of knowledge.

"Each member of the council takes the test, and then as a group we go over the questions on the exam again, to make sure it's a question worth asking and that it's still relevant, and that it hasn't been affected by regulatory changes," Delano says.

When regulatory changes mean some new questions should be asked, then something else will be eliminated, Delano says.

The council also debates how much weight should be given to any particular area on the exam, and the emphasis will be shifted according to the current regulatory climate. ■

COMING IN FUTURE MONTHS

- What do IRBs need to know about monitoring electronic traffic?
- Understanding ethics of creating stem cell donors
- St. Jude Children's Hospital tests innovative informed consent device
- Handling adolescent behavioral research

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*

1. A recent study of everyday ethical lapses among scientists found that these problems could be divided into four categories. Which of the following is not one of those four categories?
A. Meaning of data
B. Pressure to conform to longstanding practices
C. Rules of science
D. Life with colleagues

2. In organizational justice theory, what aspect describes the way in which employees are treated by decision-makers?
A. Procedural justice
B. Interactional justice
C. Informational justice
D. None of the above

3. Which two states have an age of consent for medical treatment that is greater than 18?
A. Hawaii and Alaska
B. Mississippi and Utah
C. Alabama and Nebraska
D. California and Florida

4. From 2003 to 2006, the percentage of U.S. women over 50 surveyed about research who indicated they were "just not interested in/don't believe in" participation in medical research increased:
A. Less than 1 percentage point
B. More than 6 percentage points
C. More than 10 percentage points
D. None of the above

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