IRB ADVISOR
Your Practical Guide To Institutional Review Board Management

AHC Media LLC

IN THIS ISSUE

Statement of Financial Disclosure:
Editor Suzanne Koziatek, Editor Melinda Young, Associate Publisher Lee Landenberger, Managing Editor Paula Cousins, Nurse Planner Kay Ball, and Physician Reviewer Robert Nelson, MD, report no consultant, stockholder, speaker's bureau, research, or other financial relationships with companies related to the content in this CE/CME activity.

MARCH 2008
VOL. 8, NO. 3 • (pages 25-36)

Internet research raises unique ethical concerns for IRBs

Consider the public nature of web, as well as information security

Over the past decade, the Internet has become an invaluable tool for researchers, linking colleagues across nations or even continents and enabling huge amounts of data to be transmitted quickly and securely. It even makes applying to IRBs faster and (well, relatively) painless.

But many researchers are looking to the vastness of the world wide web and seeing more — a conduit for recruiting and interviewing subjects who might not otherwise be easily contacted. And in the virtual communities that have sprung up on the web, many social-behavioral researchers see an untapped venue for studying human behavior and interpersonal relationships.

This new emphasis on Internet research has left some IRBs looking for ways to catch up to the technology and to learn how to approach the special challenges involved.

Washington University in St. Louis, MO, recently won the Health Improvement Institute's Award for Excellence in Human Research Protection in the area of innovation, for its development of a guideline for Internet research.

Sarah Fowler-Dixon, PhD, an education specialist in the university's Human Research Protection Office, says the guideline was developed because her office had noted an increase in studies that used Internet surveys and other on-line resources.

"We figured we were going to just keep seeing more of it," she says. "As protocols were coming through, reviewers were having questions about how to handle it. But we also thought it would be useful for [principal investigators], because Internet research is new for these people as well."

Similarly, after early experiences gaining IRB approval for studies that involved social networking sites such as MySpace, **Megan Moreno**, MD, MSEd, an adolescent medicine fellow at the University of Washington in Seattle, began to explore the ethical issues involved in doing research on the sites.

"I was thinking, if we were experiencing this, I'm sure there are other people who are experiencing it as well," says Moreno, whose article on the subject was published earlier this year in the journal *Pediatrics*.[1] "I feel that everybody who is doing this kind of work is just getting started, and the idea of talking about the ethics before the research gets way ahead of itself is really exciting."

IRB Advisor (ISSN 1535-2064) is published monthly by AHC Media LLC, 3525 Piedmont Road, Building Six, Suite 400, Atlanta, GA 30305. Telephone: (404) 262-7436. Periodicals postage paid at Atlanta, GA 30304. POSTMASTER: Send address changes to **IRB Advisor**, P.O. Box 740059, Atlanta, GA 30374.

AHC Media LLC is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

AHC Media LLC designates this educational activity for a maximum of 18 *AMA PRA Category 1 Credits™*. Physicians should only claim credit commensurate with the extent of their participation in the activity.

AHC Media LLC is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation.

This activity has been approved for 15 nursing contact hours using a 60-minute contact hour.

Provider approved by the California Board of Registered Nursing, Provider # 14749, for 15 Contact Hours.

This activity is intended for clinical trial research physicians and nurses. It is in effect for 36 months from the date of publication.

Opinions expressed are not necessarily those of this publication. Mention of products or services does not constitute endorsement. Clinical, legal, tax, and other comments are offered for general guidance only; professional counsel should be sought for specific situations.

Subscriber Information

Customer Service: (800) 688-2421 or fax (800) 284-3291, (customerservice@ahcmedia.com). Hours of operation: 8:30 a.m. -6 p.m. Monday-Thursday; 8:30 a.m.- 4:30 p.m. Friday.

Subscription rates: U.S.A., one year (12 issues), $389. Add $17.95 for shipping & handling. Outside U.S., add $30 per year, total prepaid in U.S. funds. Discounts are available for group subscriptions. For pricing information, call Tria Kreutzer at (404) 262-5482. **Back issues**, when available, are $65 each. (GST registration number R128870672.)

For recent permission, please contact: Stephen Vance, *Telephone:* (800) 688-2421, ext. 5511
• *Fax:* (800) 284-3291 • *E-mail:* stephen.vance@ahcmedia.com
• *Address:* 3525 Piedmont Road, Building 6, Suite 400, Atlanta, GA 30305

Editors: **Suzanne Koziatek** and **Melinda Young**.
Senior Vice President/Group Publisher: **Brenda Mooney**, (404) 262-5403, (brenda.mooney@ahcmedia.com).
Associate Publisher: **Lee Landenberger**, (lee.landenberger@ahcmedia.com).
Managing Editor: **Paula Cousins**, (816) 237-1833, (paula.cousins@ahcmedia.com).

Editorial Questions

Questions or comments?
Call **Paula Cousins** at (816) 237-1833.

Mostly social-behavioral

At Washington University, Fowler-Dixon says the bulk of Internet studies currently being conducted are social-behavioral studies, in which subjects are directed to a survey site such as SurveyMonkey to fill out an on-line form.

"I think nationally that's what people are seeing when they talk about Internet research," she says. "I'm sure it will develop from there."

Such research raises issues of the confidentiality of the sites involved and how well subjects are informed about the security of their data.

But Fowler-Dixon notes that researchers have begun attempting other types of Internet research, including observational studies in chat rooms and longitudinal studies that involve sensitive information.

She says use of the Internet for research is likely to change over time, and that the guideline needs to be a "living document" that can meet those changing needs.

"I don't write any of the guidelines to be black and white," she says. "They can't be — they have to be gray so they can be applied to various research studies."

At the University of Washington, Moreno's interest in Internet research grew out of her adolescent medicine fellowship, which has enabled her to interview teenage patients in a variety of settings.

"I would see patients in chronic pain clinics, who tend to be pretty high-achieving stressed out kids, and then I would see patients in juvenile detention or [while volunteering in] homeless clinics," she says. "And I was noticing that all the patients were talking to me about MySpace and saying it was the main thing they did, their favorite hobby. Even these homeless kids were saying we go to coffee shops and check on where all our other friends are all over the country."

Moreno became interested in examining the information adolescents post on MySpace to learn more about high-risk behaviors such as violence, substance abuse, and risky sex.

Moreno says most of her work so far has involved collecting data from viewing teens' MySpace pages or inviting MySpace participants to a survey site. Her early studies met with very different reactions from two different IRBs.

"A couple of people gave me the advice to go to the IRB and just start talking to them before I really even got started," she says. "I ended up

working pretty closely with someone at one of our university IRBs who really helped me figure out the issues that she would expect the IRB would be concerned about."

Moreno says those issues tended to revolve around consent, how to deal with underage participants or those who might lie about their age, and the public nature of MySpace.

"Was this site really public? We spent a lot of time figuring out could the average person go on there and find these things. And we quickly became comfortable saying yes," Moreno says.

When she subsequently needed approval from a different IRB, she was surprised to find that it had a completely different set of concerns.

"I got the feeling that there was a real uncertainty about what these sites are," she says. "I'd get comments such as, 'It's really unethical to read people's e-mails without telling them.' And I thought, well gosh yes, but that's not what I'm doing."

Moreno eventually got approval in both cases, but in the second instance, it required educating the IRB about how the sites work.

Public vs. private space

The use of the Internet in research — whether it involves gathering data from public sites or inviting people to fill out on-line surveys — does raise special issues that IRBs need to grapple with:

• **Intrusiveness (public vs. private space):** To what degree is the research intruding into an Internet community such as a chat room or mailing list? Is the researcher informing the group being studied or covertly "lurking" to gather information?

Washington University's guideline states that the university's Human Research Protection Office generally will require investigators to inform participants that they're being studied, by contacting a site's web master, for example.

In the case of large social-networking site, Moreno says it's clear that they are public, since anyone can access them and read the same information a researcher could.

When she talks to kids about what they post on MySpace (details of drunken binges, sexual behavior, etc.), she says she hears two responses.

"One would be total disbelief that any adult could have cracked the code," she says. "I think there is a sense among many of them that this is a place that's theirs and adults are very intimidated by it and so they can kind of do whatever they want with any discretion they want.

"The second thing I've heard is: 'I know [adults can access their pages], and I don't care.'"

• **Vulnerability of subjects:** Does the group being studied have particular vulnerabilities that need to be considered? An example might be a mailing list for victims of sexual abuse.

• **Potential harm:** Does the research or the publication of results have the potential to cause harm to an individual or to the Internet community being studied?

Moreno says that in much of her research, IRBs have determined that the risks to teens of being studied, or even being asked to participate in a survey, weren't any greater than the risks of being on MySpace in general.

"When you look at the data on predators, the number of kids who report that they have been bullied or who have been approached with unwanted sexual solicitation, it is a risky place to some degree," she notes.

She says one IRB actually saw participation in the study as a potential benefit, since the teens involved were discussing risky behaviors on their pages. The IRB reasoned that alerting the kids to how public their postings were might prompt them to clean up their pages.

• **Ages of participants:** Because it's difficult to verify the age of a participant on the web, researchers must consider how to weed out minors from taking part in a study that isn't intended for them. Some suggested methods include a posted disclaimer stating that underage individuals should not continue or asking potential participants to provide a date of birth, with a calculator determining age and either allowing or refusing to let the survey go forward.

When dealing with underage participants, parental consent is usually required. But in her article, Moreno argues that it's not always necessarily the best approach to take with adolescents. She uses as an example a 16-year-old disclosing identifiable information on a web site about drug use. A researcher may want to contact the teen to take part in an intervention to reduce that use. That recruitment, which potentially could benefit the teen, may be more successful if his or her parents aren't informed.

• **Security of information:** Fowler-Dixon says it's important to help subjects understand just how secure (or unsecure) their information might be if they participate in Internet research.

"We need to point out some things that might not be readily obvious or things that people

might not think about," she says. "An example might be if they're on any public access computer, including their work computer, then anybody can access [their data]."

She says popular survey sites are anonymous, "to a point. It can be completely anonymous, but it doesn't have to be, depending on how you use it."

The Washington University guideline calls for explaining the coding for secure sites — that only URLs beginning with "https" or displaying a padlock icon are considered secure. Participants should be reminded to completely log off the computer and to delete temporary files and "cookies" after a session to help maintain their privacy.

Researchers should be asked if information is being sent using encryption via secure sites.

• **Use of quotes in published articles:** Moreno notes that because of the searchable nature of sites such as MySpace, researchers need to be extremely careful about any verbatim quotes they use from sites, since they could lead directly back to research subjects.

"If they put a particularly revealing quote or a series of information, it is easy to search by [those keywords]," she says. "We have to realize that kids' written language is now becoming an identifier, if it's unique.

"If you type in, 'I got wasted last weekend,' you're going to get 10,000 hits. But I think the quotes that people like to use, especially for qualitative research, are the unusual ones." ■

Reference

1. Moreno MA, Fost NC, Christakis DA. Research ethics in the MySpace era. *Pediatrics* 2008;121;157-161.

Internet guideline defines research, explores issues

Consider guideline a "living document"

When **Sarah Fowler-Dixon**, PhD, an education specialist in Washington University's Human Research Protection Office, began a project to develop the university's Internet research guideline for the university, she gathered a task force of IRB members, investigators involved in Internet research, and a technical advisor to help work through the complicated security issues involved.

"Part of the reason for having a task force is to get some buy-in as well," she says. "I primarily put the guideline together and then I ran it past the task force."

Fowler-Dixon says she searched for published guidelines on the topic, but didn't have much luck. She finally learned of a white paper developed at Duke University and used it, and other information to help put together a guideline that examined the range of possible uses of the Internet in research.

The guideline defines the various types of Internet research, including on-line surveys, questionnaires that could be downloaded and mailed in or e-mailed to participants, observation of behavior on web sites, recruitment of volunteers over the Internet, and the use of large public use databases.

In addition to exploring many ethical and practical issues involved in Internet research, the guideline also includes a detailed list of standards for any secure networks created at Washington University, to ensure privacy and confidentiality of protected health information (PHI).

One area the guideline doesn't address is issues surrounding e-mailing research participants, particularly if such communications involve the transmittal of PHI. Currently, Fowler-Dixon says, the university discourages the transmittal of PHI over the Internet.

"I'm actually working on a different guideline to address that," she says. "We didn't want to mix the two because then you're talking about a lot more biomedical research. The types of Internet research I've even heard talked about at national meetings are mostly social-behavioral type things that don't involve PHI."

Over the past several months, Fowler-Dixon has been tweaking the guidelines as new information becomes available.

"As we learn more, we want to make improvements to it — add a little bit more information to it," she says.

Other institutions considering developing their own guidelines should keep the "living document" principle in mind.

"It has to be flexible enough to be applied to a variety of studies," Fowler-Dixon says. "I think the issues that we address in these studies are pretty common to information being transmitted over the Internet — not Internet research only. Issues that are more specific to Internet research are going to be the transmittal of information and then the maintenance of confidentiality because that's going to be a little bit different." ■

Video poses confidentiality and consent challenges

Videotaping subjects may require extra safeguards

Videography can be a useful data collection tool in research, giving researchers access to information — records of events, subtle non-verbal cues — that can't be elicited any other way.

But the introduction of a video camera into a research setting raises unique issues for IRBs. How do you protect privacy and confidentiality when there is an identifiable face or voice on tape? At a time when a potentially sensitive image can be uploaded to YouTube in seconds, how can researchers securely store digital images?

Researchers at the University of Pittsburgh's School of Nursing explored the ethical issues raised by the use of videography in a study of communication between non-speaking ICU patients and their nurses.

In the study, which involved patients who were intubated, videotapes of the interactions between clinician and patient were seen as a vital tool to collect data about alternative means of communication, says **Mary Beth Happ**, PhD, RN, associate professor of acute and tertiary care in the University of Pittsburgh's School of Nursing as well as assistant professor in the university's Center for Bioethics and Health Law.

But the team recognized the potential concerns about patient privacy and the security of the digitalized videos. They outlined extra steps taken to protect their subjects — both patients and nurses — in an article published recently in the journal *Nursing Research*.[1]

"We had presented some preliminary results from this work at different conferences and there was a lot of interest generated in using videotape," says **Lauren M. Broyles**, BSN, BA, RN, a doctoral student and pre-doctoral fellow at the School of Nursing. "People really were hungry for a lot of the how-to information from a technical aspect — selecting camera equipment, processing and coding the videos.

"But we also got several comments such as 'Wow, did you have any trouble with the IRB on that?'"

In fact, she and Happ say their IRB didn't raise serious objection to the videotaping, although they did ask detailed questions about video storage and what would happen to videotapes if subjects withdrew from the study.

"I think part of the reason why we didn't have a problem is because we took it very seriously and did a lot of up-front work, looking at what needed to be considered in the consenting process and on the consent form," Happ says. She notes that the team searched the literature for guidance on human subjects considerations in videotaping but was unable to find much.

Capacity to consent

The Study of Patient-Nurse Effectiveness with Assisted Communications Strategies involved the use of a small hand-held digital video camera in an ICU setting.

"I think it does help that the technology of video cameras has improved so much," Happ says. "We're not setting up the tripod, a big microphone, or lots of lights. It has a little microphone extension that's about the size and shape of a cigar and that's it."

Nurses involved in the project were consented beforehand, but patients were approached after they had been admitted and were in a bed.

An important step in the process was to assess whether the patient had the decisional capacity to consent to participate. If a patient was found incapable of consenting, family members were asked, but the patient still had to understand what was involved, including the videotaping, and to give assent.

Even if the patient was found capable of consenting to participate, family members usually were included in the discussions, says **Judith A. Tate**, MSN, RN, project director at the School of Nursing.

"Because I can imagine a family member just perchance coming upon us videotaping their sick family member who had consented," she says. "I just didn't want any surprises, or any kind of tension."

If consent was obtained through the family and the patient became decisionally capable again, he or she was asked to provide consent personally.

In explaining the study to potential participants, Tate says she would describe for the patient the entire process, including security and data storage safeguards.

"We had built into the consent that we won't be filming anything that would put them in an untoward position, for instance, videotaping hygiene or emergency situations," she says.

Patients could ask the team to stop filming at

any time if they became uncomfortable.

Despite the safeguards, Tate says some patients declined to enroll in the study because of the videotaping, while others refused because the researchers would have access to their medical records.

There also were refusals by nurses, because of concerns about their work being videotaped or because they were worried that the cameras would get in the way in the ICU.

The team obtained a federal Certificate of Confidentiality for the study, primarily for the benefit of the clinicians, Broyles says. The certificate would protect the investigators — and subjects — from having records subpoenaed by the courts in the event of a lawsuit or other court proceeding.

"Usually the Certificate of Confidentiality covers sensitive material such as sexual behavior or drug use," she says. "In this case, we were concerned about clinicians having their practice videotaped in any kind of emergency situation and then having it used in some sort of legal proceeding."

Protecting tapes' security

Once the filming was done, it was transferred to a DVD, again with extra steps taken to optimize security.

"We do not hold them on a hard drive or a server for any length of time," Happ says of the tapes. "For analysis purposes, we'd take the DVD out and view it and code it and put the DVD back into secure storage. Then, all we have [with the DVD] is numbers coded and deidentified."

Participants were asked to give consent in two parts: one for the taping itself and one if the participant would allow clips from their tapings to be shown for educational purposes. A participant could agree to the first but opt out of the second.

When the team wanted to use a particular clip at conferences or in other educational settings, they first would ensure that both patient and clinician had agreed to that use.

"If both agreed, then we use either a memory stick or a DVD that is secured to take it to the presentation venue," Happ says. "We do not send our presentations ahead of time to any venue."

The researchers don't allow their presentations to be videotaped at conferences, and are careful to delete any video clips from the podium computers before they leave.

"That's probably overkill, because the participants did say we could use them," Happ says. "But when we started this in 2001, there wasn't easy access to video through YouTube, and sites like that. We just feel like we need to be extra careful."

Broyles says that IRBs considering a protocol that involves videography should consider several potential concerns:

- **Informed consent issues**: The potential for patients to be identifiable through a videotape adds an extra layer of concern when assessing a patient's decisional capacity, Broyles says.

"You have people who have altered mental status because of their illness or because of their medications, so I think it's pretty paramount to do an assessment," she says. "You have the ability for proxy consent, but then it's important to return to the person once they become more alert and ensure that they still want to continue."

It also may benefit subjects to give additional consents for different potential uses of the video.

If patients withdraw from the study, it should be clear whether they will allow use of any videotaping to that point, or if they are denying such permission, which would prompt the need to destroy the recordings.

- **Privacy and confidentiality:** Broyles says that in some studies, it may be possible to blur faces or place black bars over subjects' eyes to protect identities. In their own study, however, that was not possible, since it would have masked the information they were trying to collect.

"It's about communication between nurses and patients, so we needed to be able to see faces," she says.

Care should be taken to protect patient modesty in clinical settings, and to protect other patients, clinicians, and family members from inadvertently being taped.

- **Data storage and access:** How will the videos be stored, and for how long? Will images be stored on a computer for any length of time?
- **Participant burden:** Will videotaping in a clinical setting cause stress or anxiety in patients or clinicians? What steps will be taken to keep equipment and personnel out of the way?

"Videotape is the best way to gather data on communication," she says. "But I think the gratuitous use of videotaping would be worrisome. I would want to make sure that the use of the videotape matches the research question and that there aren't other ways that the data can be safely and accurately obtained without the use of videotape.

"Videotaping is a new, appealing, popular medium that more people have access to and have become technically comfortable with, and you have to worry that it could be overused."

But in cases where it's an appropriate tool, Broyles says IRBs shouldn't shy away from allowing it.

"Traditional human subjects protections can easily be applied to this situation," she says. "There isn't necessarily a need for IRBs to be overly squeamish or for serious red flags to fly up, as long as some of these particular considerations are examined." ■

Reference

1. Broyles LM, Tate JA, Happ MB. Videorecording in clinical research: Mapping the ethical terrain. *Nurs Res* 2008;57:59-63.

Research project developed active, engaged consumer advisory board

CAB helped with recruitment, IC issues

When a Boston, MA, research team decided to study HIV/AIDS prevention among the mentally ill, a group that is particularly vulnerable to infection with the disease, they had to ensure their research volunteers were recruited with appropriate privacy safeguards and thoroughly understood their research participation.

"We're targeting a population of people who by the nature of psychiatric disorder are vulnerable, and we're targeting the prevention of a disease where there's a lot of stigma," explains **Stephen Brady**, PhD, an associate professor of psychiatry and graduate medical sciences and the director of the mental health and behavioral medicine program at Boston University School of Medicine in Boston. Brady is the principal investigator of the study on HIV prevention with the mentally ill.

So investigators created a consumer advisory board (CAB), which along with the IRB, provided guidance in recruitment and informed consent.

"The consumer advisory group was our idea, and it was encouraged by the National Institute of Mental Health," Brady says. "You don't have to have a consumer advisory board, but, increasingly, I think CABs are going to become the standard for these kinds of studies."

The CAB consists of 8-10 people, who either have a mental illness, are HIV-positive, or are impacted by these illnesses. Members meet monthly and have contact between sessions, he says.

The board has even assisted research staff with pilot testing the study's assessment instruments, says **Jori Berger-Greenstein**, PhD, an academic rank assistant professor in the department of psychiatry at Boston University School of Medicine. Berger-Greenstein is the project director of the HIV prevention study.

CAB members were recruited through a consumer advisory group of people with mental illness in Massachusetts and from a center for HIV/AIDS care and research.

"We brought the two groups together to create a unique consumer advisory board," Brady says.

A leaders in advocacy for mental illness aggressively recruited CAB members and even escorted people to the meetings, and HIV/AIDS advocates also were very helpful, he notes.

The board has changed and evolved as some people left the area or their mental illness or disease proved too burdensome, Brady says.

"I've been on other studies and have had experience with other boards," Berger-Greenstein says. "Often it's something researchers do to say they're doing it, but they don't take it very seriously."

Likewise, the people running the CABs often lack active interest in the study and their role, she says.

But the CAB for the mental health and HIV prevention study has been extremely engaged and helpful to the research team, Berger-Greenstein says.

One key has been Brady's active participation.

"It is important to them that the head scientist in the study cares about them and wants to hear from them," Brady says.

"A lot of time people do the boards, and then they aren't given much to do,"" Brady says. "Our board is very active."

For instance, the CAB has helped with interviewing and training direct care staff for the study and vetted subject recruitment materials, Brady says.

CAB members also have helped pilot test the assessment instruments by pretending to be potential subjects and answering instrument questions. They gave researchers feedback on whether an instrument was too long or intrusive, he says.

"They did the initial outreach at various community organizations where they thought there'd be large numbers of people with mental illness

and who were at risk for HIV," he adds. "They went to women's shelters and talked to the staff they knew there, or they put up fliers for us, sometimes giving a talk themselves."

The CAB also has helped provide additional safeguards for participants recruited in the trial.

Here are some the ways the research team has ensured maximum human subjects protection:

• **Protect identities:** The IRB required that researchers not identify potential participants by name in the screening process, Brady says.

"We don't identify people by name at all, and we think it is a good idea," he adds.

"We only ask people if they have a mental illness, and we give them a menu of illnesses," Brady explains. "We don't ask them which illness they have, and we don't ask about specific HIV risk behaviors, but give them a menu of behaviors and ask if they've engaged in those."

This way, researchers can gather important screening information without potentially harming the potential participants, he says.

And this is done before people agree to enroll and informed consent is provided.

• **Do not recruit directly:** It's important to many IRBs that researchers do not directly approach potential participants and request their participation, Brady says.

"We can use general advertising, and people can self-refer and providers can self-refer," he adds. "But we don't approach patients directly to solicit their participation."

Instead, researchers relied on referrals and advertising and assistance from the CAB.

• **Assess participants' understanding of the informed consent language:** "We go to great lengths to make sure our informed consent document is detailed, but also we spend a lot of time discussing that with patients," Brady says.

"We ask them questions about what they understood about the study, and we engage in an ongoing dialogue to make sure they understand the particulars of this study," he adds.

Researchers focus on making certain participants understand that their treatment will not be impacted by their participation in the study.

"We want them to know they can get out of the study at any time and change their mind," Brady says.

Investigators evaluate potential participants' appropriateness for being enrolled during the informed consent process, as well, Berger-Greenstein notes.

"When we do informed consent, we have them repeat things back," Berger-Greenstein says. "We're very careful to make sure they're intact enough to participate."

For example, one young woman who wanted to enroll in the study was discovered to be suicidal, so she was referred to a psychiatric emergency room rather than being enrolled in the study, Brady says.

"The welfare of the people we're helping takes precedence," Berger-Greenstein says.

If participants are determined during the informed consent or screening processes to need medical help, they can be referred to nearby services since the research is taking place within a large medical campus, Brady says.

"Another way to look at this safeguard is that we're a full service agency campus that can triage people appropriately if their mental health status is unstable," he adds. ■

Revisit your conflict of interest policies to ensure comprehensive coverage

MDs say COI indiscretions happen

IRBs and research institutions occasionally should revisit their conflict of interest policies and update them to make certain they effectively protect human subjects, as well as pass the "smell" test.

Passing the "smell" test might be the more difficult challenge.

Consider the fact that most clinical investigators have had some sort of relationship with pharmaceutical companies.

"These can range from friendly visits with drug reps, where they leave you pens and notepads to five-figure consulting agreements or speaking fees," says **Brad Noren**, MA, CIP, research and contracts administrator for Oregon Health and Science University in Portland, OR.

"Once you've realized that there is this very pervasive relationship between physicians and companies developing drugs and devices, then you have to step back and figure out how it best can be managed," Noren says.

Recent literature strongly suggests that physicians are aware of these interactions with industry and the potential or appearance of conflict of interest, Noren notes.[1-4]

"But, interestingly, it's been shown that they readily suggest that their colleagues are more easily influenced by these drug rep visits than they are themselves," he says.

A common threshold for a financial COI is $10,000 to $15,000," Noren says. "But even when you set the threshold, $10,000 for a physician who makes six figures a year is quite a different thing that it would be to a lab technician or junior researcher."

And when a financial COI is revealed to the general public, it often sounds worse than it is: "If your Joe Citizen brings home $25,000 a year, then a $10,000 annual consulting fee for a few hours of work seems rather outrageous," Noren says.

One way to update the COI policy would be to have someone other than the investigator decide whether a particular relationship poses a conflict and needs to be changed, Noren suggests.

Here are two questions to ask when assessing a potential COI:

- Would this relationship look to a reasonable person like a competing interest is exerting an undue influence on the research?
- And if the PI is also a physician, does unrestricted gift money from the company somehow influence the physicians' prescribing patterns?

Answering those two questions in advance would provide some COI protection to the physician/PI and put the PI above the appearance of an improper relationship, Noren says.

"Some methods of managing a conflict of interest include letting the investigator keep stock in the company, but not letting him be involved in analysis of data," Noren says. "He will not be the one to review the inclusion/exclusion criteria and enroll subjects."

Another management option would be to have the investigator divest himself of the stock, but that would be in an extreme case, Noren says.

"That's certainly something that a COI committee would be justified in at least offering as one possible solution to the investigator," he says.

Some medical campuses are even taking the extreme action of managing potential COI by not allowing pharmaceutical company representatives to visit their campuses, Noren notes.

For example, the University of Pennsylvania School of Medicine published in 2007 its policy to strictly regulate the activity of pharmaceutical representatives by prohibiting meals and gifts.[3]

"The American Medical Student Association [Reston, VA] has come out strongly against doctors receiving gifts of any kind, and they argue the awareness of this potential conflict must be a more prominent part of the medical professional's education," he says.

"So people on some campuses can't take a pen or gift or accept lunch," Noren says. "It's possible that this will be a trend that spreads, but it's a decision that has to be made at an institutional level, and you would have to have buy-in from faculty." ■

References

1. Wall LL, Brown D. The high cost of free lunch. *Obstet Gynecol* 2007;110:169-173.
2. Schramm J, Andersen M, Vach K, et al. Promotional methods used by representatives of drug companies: A prospective survey in general practice. *Scand J Prim Health Care* 2007;25:93-97.
3. Wasserstein AG, Brennan PJ, Rubenstein AH. Institutional leadership and faculty response: Fostering professionalism at the University of Pennsylvania School of Medicine. *Acad Med* 2007;82:1049-1056.
4. Collins J. Professionalism and physician interaction with industry. *J Am Coll Radiol* 2006;3:325-332.

Best Practices Report:
Improve orientation, training

Improve your IRB's orientation & continuing education for members

Columbia University's IRB offers tips

It might take an individual IRB member from six months to a year to become fully acclimated to participating on an ethics board. So research institutions should do what they can to improve both new IRB member orientation and continuing education and training.

"We focused on orientation early on, and now we realize it's a continuing process," says **Brenda L. Ruotolo**, CIP, associate director of the Columbia University IRB office in New York, NY.

IRB members need to receive continuing education for several reasons:

- **IRB members need to handle diverse protocols:** IRB members often are asked to review a wide variety of research, which means that it takes time to build competence and experience.

"Most of our IRB members are on the board

for at least three years, and many are on the board for longer than that," Ruotolo notes. "We are a large institution and have large volumes of protocols, and our boards on the medical center campus are not specific, which means IRB members on any board will see any type of research."

Columbia University's IRBs include one that reviews primarily social science and behavioral research and three on the medical center campus that review the full range of biomedical research.

• **IRB reviews are becoming more complex:** The work that IRBs are doing is more complex with a wider range of protocols and the addition of genetic research into the mix.

"We have a school of public health on the medical center campus, and the IRB will see social science, behavioral epidemiology, and many biomedical projects that have a behavioral component, including questionnaires," Ruotolo explains. "All of the IRBs are seeing more genetic research because there's a genetic testing component in many of our protocols."

For example, some clinical trials might involve a look at markers for genes that predispose people to a condition or to a response to a condition, she adds.

"All of the IRBs are seeing crossover research," Ruotolo says. "Starting with behavioral interventions, investigators are asking subjects questions or showing them stimuli and looking at their brain responses through a magnetic resonance imaging [MRI] device."

As this trend continues, increasing numbers of IRBs will no longer specialize exclusively in reviewing only social-behavioral research, Ruotolo predicts.

• **Learning the basic ethical guidelines, regulations, and history takes time:** "So even though we have reviewers who come to the IRB because of their expertise, it takes a while to understand how the regulations are applied to research," Ruotolo says.

Plus with the emphasis on crossover research, IRB members need to understand a greater range of ethical issues.

• **Almost all IRB members are potential primary reviewers:** All of the members of Columbia's Morningside IRB, which consists primarily of social scientists, behavioral scientists, and nonscientists, could be a primary reviewer for a protocol, Ruotolo says.

"On the Columbia medical center campus IRBs, it would be unusual for us to assign a nonscientist to be a primary reviewer for a biomedical protocol," she notes.

Even so, nonscientists could be secondary reviewers, so it's important that the training be adequate for either role.

To begin training for new IRB members, the institution provides a two-hour orientation session that may be a one-on-one session or a workshop with several attendees.

"We talk about the history of IRBs and the mission of IRBs," Ruotolo says. "It's important that we focus on how IRBs protect human subjects."

This mission is emphasized particularly for the benefit of clinician members who are accustomed to focusing on their medical responsibilities with regard to protecting patients, themselves, and their institution against medical risks.

"But for the IRB they need to focus solely on the research subject because that's who we're protecting," Ruotolo says. "It's not our responsibility to worry about risk to the institution or investigator.

"When we move over to the IRB, the focus is absolutely and singly on protecting the subject," Ruotolo says. "It's important for us to have them understand that, and in most cases, they are able to do so."

The orientation program also covers regulations that apply to human subjects research and IRBs, and there's an introduction to the Belmont Report, Ruotolo says.

IRB members learn the difference between human subjects protection regulations postulated by the federal Department of Health and Human Services and the FDA regulations that apply to research.

"A two-hour discussion is not enough to go into details about these, so we give new IRB members some materials, including a book that lists the regulations and has an overview of the IRB process," Ruotolo says. "We think it's a good reference."

The orientation also touches on the institution's own policies and procedures, including what the IRB staff does to assist the IRB and what IRB members need to do to prepare for each meeting.

For instance, the IRBs at Columbia meet twice a month for several hours at a time, and members are expected to do some homework before each meeting, Ruotolo says.

"We screen potential IRB members to see if they can handle the commitment as well as their other duties," Ruotolo notes. "We'll assign some people as alternates who can fill in on the IRB for

regular members."

Part of any education and training includes marketing. So new IRB members are taught that their role isn't all work.

"There's an opportunity for them to interact with their colleagues on a different level than they do clinically," Ruotolo says. "They can discuss new technologies and procedures that are coming through, and they are able to see the new research and provide valuable service to the community."

Many IRB members find it to be very rewarding work, Ruotolo says.

The orientation session also discusses the IRB office's electronic submission process, but there is a separate training program for learning to use that system.

"Then we talk a lot about the processes, how IRB meetings are run, how we need a quorum, and we try to impress upon new members that the IRB is not a scientific review board," Ruotolo says. "It's an ethical review board."

Occasionally the IRB will receive protocols where the study is not well put together, but it's not the IRB's job to evaluate the science unless the science is so poor that it puts people at risk, Ruotolo says.

"Then it becomes an ethical decision that there couldn't be valid data that comes out of it," she adds.

"The other thing we impress upon them is they shouldn't spend a lot of time wordsmithing," she adds. "We need certain elements and information in the informed consent document, but it may not be worded exactly the way an IRB member would like to have it worded."

As long as the main concept is there and the informed consent form is comprehensible to subjects then it needs to go forward, Ruotolo says.

For continuing education, there are relevant topics discussed at each IRB meeting.

"We discuss with IRB members a topic that's relevant to the research we're seeing," Ruotolo says.

These short educational pieces take about 5-10 minutes of the meeting time, and they're summarized on a one-page handout.

"We've tried half-hour educational sessions at the beginning of the IRB meeting, but the boards don't have time to devote to that," Ruotolo says. "It's not a commitment they can make."

The topics selected have included information about informed consent, criteria for waiver of consent, and other issues that have ongoing importance or might be especially relevant to a particular IRB review, Ruotolo says.

"A staff member for that IRB will present the topic and restrict the time to 10 minutes or less," she explains. "The staff member will give the board a handout, and there's an opportunity for discussion."

Basically, the educational session is an introduction. IRB staff members send follow-up information to the board electronically, Ruotolo says.

"We've had good response to this and often introduce new policies this way, as well as new interpretations of the regulations," she says. "If we see some kind of research being reviewed that's different from what we've seen before we'll feature that as a topic."

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

COMING IN FUTURE MONTHS

- IOM committee studies effects of HIPAA Privacy Rules on researchers, IRBs
- Best practices: Check out this new form development process
- Behind the scenes of the OHRP controversy over infection control checklist
- Protecting subjects in pain research

Other educational opportunities include monthly investigator meetings which some IRB members attend, and there's an annual IRB conference, held in April, that's open to outside institutions, Ruotolo says.

"We decide which topics will be presented based on feedback from IRB members and chairs," she says. "We try to address challenging issues like genetic research and testing and informed consent issues."

The conference typically features nationally recognized speakers and is well attended by IRB members, she notes.

Although the orientation and continuing education are basically the same for IRB members, regardless of their scientific background, the individualized attention gives everyone the attention they need, Ruotolo says.

"The role of the nonscientist is very important on the board, and we want to emphasize what that role is," she explains. "So our orientation for them would be a little different and address more of those kinds of issues important to their unique presence on the board." ■

CE/CME *questions*

9. Which of these steps should on-line research subjects be encouraged to take to protect their privacy?
   A. Look for a padlock icon or the letters https in a web address to ensure a site they're using is secure.
   B. Completely log off a computer when finished with a survey session.
   C. Delete all temporary files and cookies after a session.
   D. All of the above.
10. Verbatim quotes taken from web sites and used in articles can pose a risk of revealing a subject's identity.
   A. True
   B. False
11. A community advisory board (CAB) can help ensure human subjects protection in a behavioral study by providing which of the following services?
   A. Help with pilot testing of intervention tools used during study
   B. Review recruitment materials
   C. Meet regularly to discuss the trial and its impact on target population
   D. All of the above
12. Which of the following is a good reason for IRBs to provide continuing education to members?
   A. IRB protocols often are very complex
   B. IRBs frequently review a diverse range of protocols
   C. Learning the basic research ethic regulations is time-consuming
   D. All of the above

Answers: 9. (d), 10. (a), 11. (d), 12. (d).