IRB ADVISOR

Your Practical Guide To Institutional Review Board Management

THOMSON
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Special Report: Students and research protection

Student volunteers don't give up their right to human subject protections

Colleges may have to change how they recruit students

Recruiting students for research at universities and colleges is no longer as simple as having professors offer extra credit in exchange for participation. It has become an area that has created controversy within institutions and IRBs.

For years, universities and, specifically, their psychology departments have used students as research subjects under the premise that participating in research is an educational experience with potential benefits for involvement in the process, says **Steven Taylor**, PhD, education professor and IRB chair at Syracuse (NY) University.

"If you are trained to do research and conduct experiments, then it's useful to have personal experience on the other end of that," he says. "It makes you more sensitive to the rights of subjects."

So the programs that have been doing research with students for years became set in their ways, and now it's up to IRBs to educate departments, professors, and investigators about why changes are needed in how students are recruited and used for research, Taylor adds. **(See story on issues of students in research, p. 63.)**

"I think all IRBs these days are going through this process of clarifying policies, being as explicit as possible to investigators about federal requirements and regulations," he says.

The philosophical evolution in how institutions and IRBs view the use of college students as human subjects is a positive change, says **Mike Breton**, PhD, associate vice president for research and sponsored programs at Rutgers University in New Brunswick, NJ.

"Faculty are in demand of large numbers of students for relatively innocuous and low-risk studies, but they do still need to be protected from exploitation," Breton says. "The sensitivity is that maybe the study doesn't pose risk, but just simply coercing the student into the study is

not the right thing to do."

Rutgers has a policy that requires faculty to offer alternative ways for students to meet any course requirements that involve participation in research and, within the first week of classes, to give students a written description of the various ways they can meet these requirements.

Syracuse University's policy specifies how students may be offered extra credit to participate in research provided six conditions are met, including the requirement that the investigator submits the recruitment flyer or sign-up sheet to the IRB and that a nonresearch alternative of comparable time is offered for the same amount of credit.

"Students are very susceptible to the pressure to earn good grades, and they are not going to complain about these kinds of things, which is why IRBs need to be aggressive about these issues," Taylor notes.

For example, at Western Kentucky University (WKU) in Bowling Green, a professor and principal investigator found that having sign-up sheets for class credit was a good incentive for recruiting students as research subjects, but when the research was set to begin, only 50% of the students would show up, says **Phillip Myers**, PhD, executive director of WKU and director of the Office of Sponsored Programs.

So one professor began to penalize the no-shows through their class grades, and suddenly 90% of the students would show up to participate. However, when the university's IRB learned of this practice and reviewed it at a meeting, the IRB decided that researchers could not penalize students for failing to show up because this was too coercive a practice, he says.

"You cannot penalize human subjects for signing up for an experiment and not showing up," Myers says.

Any research that offers credit incentives for students participating in research also has to have an alternative method for obtaining the same credit, such as writing a short paper, and this has to be clearly stated in the course syllabus, he says.

WKU is one of a growing number of universities that has had to revisit the issue of student participation in research to determine whether existing policies need to be updated and revised.

The IRB at Syracuse University has also looked at the issue of penalizing students who sign up and then don't show up, and has reached the same conclusion.

"You have the right to withdraw from research without penalty," Taylor says.

To fulfill the spirit of the right to withdraw without penalty, students have to be provided at least partial, if not full credit, if they decide not to participate, Taylor says.

"Some academic departments, I think, are using students inappropriately," Taylor says.

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Editorial Questions

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

"And the difficulty with the IRB is that you can't monitor everything that everybody is doing."

The Syracuse IRB's general policy is that students can be used as research subjects as long as they're offered an alternative, nonresearch activity of comparable time and effort, Taylor says.

"The way our programs do it here is they don't make participation in research a course requirement," Taylor adds. "And when they offer extra credit, students have a clear opportunity to do nonresearch activities."

The IRB at Miami University in Oxford, OH, carefully reviews research that recruits students as subjects for any signs of coercion or potential coercion, says **Carol B. Willeke**, PhD, associate director in the Office for the Advancement of Research and Scholarship.

"We don't allow people to give extra credit as incentives to research participation," Willeke says.

The university has a psychology pool in which students can participate in order to fulfill certain research credits, but this is not the same as extra credit within a particular class, Willeke notes.

"If a student is in a class with a professor doing research that semester, then someone in place the professor will ask students to volunteer to participate in research," Willeke explains. "The professor will not know who has agreed and who has not agreed until after the grades are assigned for the semester." ■

Special Report:
Students and research protection

Student recruiting raises issues, concerns for IRBs

Researchers, IRB officials offer advice

College student populations may offer a plentiful and accessible source for human subjects research, but IRB and university research officials say that a variety of issues arise when students are used, and it's important for IRBs to address these in policies and procedures.

Here are some of the issues that arise when students are recruited for research:

• **Selecting an equivalent alternative activity:** When universities permit instructors to issue credit for research participation, there must be an alternative way that the student can earn the same credit. IRB members and others say this area is one that IRBs need to carefully review, because what looks like an equivalent alternative to professors may not seem equal to students.

The alternative to research participation cannot be more onerous, and it should be made public to students, says **Celia Walker**, MA, director of the Regulatory Compliance Office at Colorado State University in Fort Collins.

The IRB at Syracuse (NY) University saw a red flag raised regarding this issue when one protocol called for offering students extra credit for signing up for one of a variety of research projects that each would take about an hour to 1½ hours of student time, says **Steven Taylor**, PhD, professor of education and IRB chair.

"This department offered students a nonresearch activity that was a 10-page research paper," he says. "You can see why that reached our attention, because there is no way to write a 10-page research paper in one to 1½ hours."

Offering students such a time-consuming alternative to research participation constitutes undue coercive pressure, Taylor adds. "No student would take the nonresearch alternative, so that's one issue that has concerned us."

When Taylor questioned the investigator about this unequal alternative, the investigator replied that the 10-page paper would take comparable time and effort. "I said, 'No, it would not,'" he says.

At Rutgers University in New Brunswick, NJ, students may be given the alternative of writing a two- or four-page paper, depending on the intensity of the research study, says **Karen M. Janes**, associate director of research integrity and compliance in the Office of Research and Sponsored Programs.

"When you participate in the psychology department as a student, you have a choice of signing up for the subject pool or opting not to and doing an equivalent paper," Janes says.

• **Recruitment incentives:** For college students, grades and credit are more enticing incentives than cash, so IRBs need to be very careful in reviewing protocols for potentially coercive incentives, IRB members say.

"If you offer a student an extra grade or 20% more credit, then that is enticing them with their gold standard, and it probably is more valuable to them than $50 or $100," says **Carol B. Willeke**, PhD, associate director of the Office for the Advancement of Research and Scholarship at Miami University in Oxford, OH.

The question IRBs need to ask is whether the

incentive is coercive.

Mercer University in Macon, GA, has addressed this issue in its written policy on "Selection and Recruitment of Subjects in Research Investigations" with the following statement: "Potential subjects should not feel coerced into participating in research, nor must they fear the loss of some benefit to which they are otherwise entitled if they choose not to participate. A person in authority, such as a teacher recruiting students or a physician recruiting patients, should take precautions to ensure a potential subject's decision to participate in research is not based on subtle pressures such as grades or a fear of loss of benefits, like medical treatment."

• **Handling college students as subjects when students are minors:** It's not uncommon for college students to be under age 18, so an institution and IRB will need to revise policies for how recruitment can take place when student subjects are underage.

About 15% of the incoming freshmen living in residence halls at Colorado State University are younger than age 18, Walker says.

"So if those students are involved in research projects for intro psych or another class, they can only participate with parental permission unless parental permission can be waived," Walker says.

Some institutions may handle this by sending parents at the beginning of the semester a standard parental consent form, asking whether they give approval for their son or daughter to participate in research experiments and to state what is clearly unacceptable, Taylor notes.

But this isn't adequate for informed consent, Taylor explains. "Parental consent has to be specific to the research study, and parents have to be aware of the benefits or risks."

• **Monitoring off-campus research recruitment:** Another issue that occasionally will cross an IRB's desk involves the recruitment of a college's students for research that is conducted by an organization not affiliated with the college or university.

The IRB at Towson (MD) University was alerted several years ago to a problem involving an outside study, says **Patricia M. Alt**, PhD, IRB chair and professor of health science.

A flier had been circulating on the campus for a study of how quickly alcohol and antihistamines, when taken together, would clear out of a person's system, she recalls.

"Someone brought us the flier, and we flipped out," Alt says. "We had mental images of people getting drunk and driving up the expressway, banging into things."

After further investigation, the IRB learned that the study, which was conducted by another university and reviewed by its IRB, would involve having participants spend the night after observation, and it would carefully screen out all students younger than age 21, she says. ■

Special Report:
Students and research protection

IRB monitoring varies for student researchers

Proposals may fall under radar

IRBs located in universities might find themselves inundated with low-risk protocols if they reviewed every single study proposed by college students working on their graduate papers.

On the other hand, it would be poor policy and possibly provide risk to human subjects if these studies were routinely ignored.

One way to look at the situation is to see the monitoring of protocols submitted by student researchers as an opportunity to continue educating fledgling investigators about research ethics and the protection of human subjects.

"Our biggest interest is in making certain students learn something in the process about how to do research," says **Patricia M. Alt**, PhD, IRB chair and professor of health sciences at Towson (MD) University.

"Sometimes we have students who are overeager and submitted protocols to the IRB that they didn't need to submit because it wasn't really research," she says. "Sometimes a new faculty person has everyone submit an IRB application because they were going to collect information from friends on their statistics of height, eye color, etc. — not generalizable knowledge, not research."

In these cases the IRB will tell the teacher that while it's good that they want to teach their students about the IRB process, this type of application should not be submitted because it's not for research, Alt adds.

While the IRB does not require every student working on a master's thesis to submit a protocol,

the IRB does review any research done by a student for the purpose of collecting data from human subjects that will make a generalizable contribution to science and which will be published in the university's library.

Other IRBs take an even more stringent stand on research conducted by students.

"Graduate students as investigators are supposed to follow the same standards [as principal investigators]," says **Karen M. Janes**, associate director of research integrity and compliance in the Office of Research and Sponsored Programs at Rutgers University in New Brunswick, NJ.

"Their advisor signs off on the protocol, as well, and the advisor takes the human certification test," she says. "We carry it a step further here at Rutgers."

Even when students are conducting the type of surveys that fall short of federally defined human subjects research, Rutgers requires the student investigators to submit the proposed protocol to the IRB, Janes adds. "We want to make sure they follow the standards when they're gathering information and representing Rutgers."

At Towson University, graduate student researchers are given a packet of information that details the types of research that must be approved by the IRB, and a faculty advisor must sign the student's protocol application, ensuring that it is scientifically valid, Alt says.

"Also, members of the IRB talk to graduate classes about human subjects research, including groups doing master's projects," she says. "We have workshops about human subjects research several times a year for students and faculty."

Student researchers at the New England School of Acupuncture in Watertown, MA, must have a faculty member monitoring their project, says **Barbara Marcel**, RN, PhD, research advisor.

Also, she oversees student projects and works with students on their academic research, and everyone involved in research must take an online research ethics course and quiz. "So they get more monitoring than what a principle investigator would get," she says.

This sometimes means that a student's initial ideas for a research project are shot down.

"I have had students call me, saying, 'I have a friend who's a nurse doing a project with attention-deficit, hyperactivity disorder, and I want to do that for my research,'" Marcel recalls. "But when the student sent me documents about the research, I could see it did not have an IRB's approval, and so I said, 'No, you can't do that project.'"

Before the school had its own IRB, students were permitted to work in collaboration with another institution that had IRB approval and followed federal guidelines for a particular research project, she says. "Now we wouldn't do that because everything has to go through our IRB as well." ■

IRBs have a new charge: Authorization waivers

It's up to the researchers to justify waiver

It started out a simple premise: protect patients' privacy by securing their health information. But the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA) is raising some concerns, not just among primary caregivers and treatment facilities.

There is much to be confused about if you're involved in research. To begin with, the regulations state that the Privacy Rule is not directly aimed at research. But there is a caveat: If the research involves access to information, then the Privacy Rule *may* apply. At issue is information derived from covered entities — health plans, health care providers, or health care clearinghouses that transmit information electronically. Those covered entities are required to keep prying eyes from patients' private health care info (referred to in HIPAA guidelines as protected health information or PHI), which includes diagnoses, treatment courses, and payments related to treatment.

Given that most research will involve patient information deemed private under HIPAA, researchers and IRBs must now learn to incorporate Privacy Rule requirements into their protocols.

"HIPAA adds another layer to the IRB approval process," says **Lisa Sotto**, JD, a privacy regulatory specialist at Hunton & Williams in New York City. "One significant concern of IRBs is how researchers will safeguard information when data in maintained in so many downloadable formats."

The Department of Health and Human Services (HHS) issued a guidance document, "Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule," to help researchers and IRBs understand just what is required under HIPAA. The guidance, available at http://privacyruleand research.nih.gov/pr_02.asp, tries to cover everything you'd ever want to know about HIPAA, including definitions on pertinent

terms you may encounter and various aspects of the rule that may impact research.

Informed consent vs. authorization

The terms are being used interchangeably but they should not be. "Informed consent provides the research subject with a description of the study and its anticipated risks and benefits," says Sotto. "A HIPAA authorization is the participant's permission to allow the investigator to use and share information in ways that are specified in the authorization form."

Though the consent documentation and authorization agreement can be combined, the authorization form should contain specific elements, such as what information can be used, to whom it can be disclosed, whether participation is dependent on the participant's signing the authorization, and the participant's signature.

According the HHS, authorization forms can be written by researchers and do not require IRB approval. Additionally, according to HHS regulations, one waiver is all that is required for multisite projects.

IRBs get involved, however, when an authorization alteration or waiver is requested. The HHS states: "A complete waiver occurs when the IRB or Privacy Board determines that no authorization will be required for a covered entity to use and disclose PHI for a particular research project."

In deciding whether to grant an authorization waiver, IRBs should be looking at how sensitive patient treatment info is. "If you're dealing with genetics or HIV data, the IRB is going to want to see serious privacy protections in place," says Sotto.

IRB waivers should contain language that describes the following:

- that the research poses no more than a minimal risk to the privacy of individuals;
- that the research could not be conducted without the waiver;
- that the research could not be conducted without access to and use of PHI.

"IRBs are charged with protecting the confidentiality of research subjects," says **John Isidor**, JD, CEO of Schulman Associates IRB in Cincinnati. "The waiver is designed to allow a person's PHI to be used and/or disclosed for research purposes without the person's authorization. The researcher must assure the IRB among other things that there is minimal risk to the person's privacy and that the research could not be conducted without the waiver." **(See form, inserted in this issue.)** ■

HHS guidance on financial conflicts puzzles some

Some call it vague

The U.S. Department of Health and Human Services (HHS) has managed to calm some concerns about federal guidance on financial conflicts of interest and research, but new issues have arisen.

Unlike the proposed guidance published several years ago by the Office for Human Research Protection (OHRP), the draft guidance published March 31, 2003, in the *Federal Register* offers more questions to be considered than specifics to be followed.

The toned-down approach appeals to some people who had comments and criticism of the earlier guidance.

"They had softened it to a great extent from the language of that earlier guidance, which didn't seem like guidance at all because it had a tone of how IRBs should do this and they shouldn't do that," says **Ann J. Gellis**, JD, associate dean for research compliance in the Office of Research and University Graduate School at Indiana University in Bloomington.

The current guidance proposal is more flexible and will allow different organizations to fashion their own policies to fit their institutional and organizational needs, she adds.

Others find fault with the guidance's flexibility.

"I felt it was overall too vague," says **Steven C. Schurr**, an attorney in Chicago. He represents site management organizations and has worked as a clinical monitor for research.

Although the guidance offers some examples of conflicts of interest, it is vague on the details of resolving conflicts of interest, he says.

"The part that concerns me the most is the last section about receiving payment per participant," Schurr says.

The guidance asks IRBs and institutions consider ways to examine the issues, including whether individuals or institutions receive payment per participant or incentive payments and whether those payments are within the norm.

Schurr says he wants to know what the norm is and how an IRB or institution may determine when a payment falls outside this norm. The federal guidance offers no more information on the matter.

This point is particularly important to site management organizations, which are small businesses

Conflict of interest questions in a nutshell

Stanford University's IRB form

The Stanford (CA) University protocol application form includes a section that examines potential conflict of interest through seven questions.

If an investigator answers "yes" to any of the questions, then he or she must include a statement in the consent form to disclose the relationship and which institutions or companies are involved in the study through funding, cooperative research, or by providing study drugs or equipment.

Also, the investigator must file a conflict of interest disclosure with the appropriate school dean, and the university's conflict of interest committee will review the information. Questions include:

- Do any of the involved investigators or their immediate family (meaning spouse, dependent children, or domestic partner) have consulting arrangements, management responsibilities or equity holdings in the sponsoring company, vendor(s), provider(s) of goods, or subcontractor(s)?
- Do any investigators or their immediate family have a financial relationship with the sponsoring company, including the receipt of honoraria, income, or stock/stock options as payments?
- Is any investigator a member of an advisory board with the sponsoring company?
- Do any investigators receive gift funds from the sponsoring company?
- Do any investigators have research grants for other protocols from the sponsoring company?
- Do any investigators or their immediate family have an ownership or royalty interest in any intellectual property utilized in this protocol?
- Does Stanford University have an ownership or royalty interest in any intellectual property utilized in this protocol? ■

affiliated with a clinic for the purpose of research, he says.

"These companies subsist on landing pharmaceutical contracts," Schurr explains. "The way the contracts are written they get paid per patient they enroll, so their whole revenue comes from this, and everyone's job depends on their getting contracts and enrollment."

One could argue that such arrangements are inherent conflicts of interest and there is an incentive to enroll patients who don't fit the criteria, he notes. "But pharmaceutical companies want good data — not bad data, and they monitor and reward sites for doing a good job."

So Schurr's question is whether these arrangements are something that should be noted by the IRB as a conflict of interest and whether a conflict of interest committee needs to make a determination about such an arrangement and require corrective action.

One early comment submitted to HHS about the guidance suggested that the addition of a waiver would make the guidance stronger and provide better human subjects protection.

In the first comment submitted to the Food and Drug Administration, posted April 4, 2003, the Alliance for Human Research Protection of New York City, suggested that HHS include with its guidance a model affidavit that investigators, IRB members, and others would sign to attest to their having no significant conflicts of interest.

However, some university research officials say they already have checks and balances in place, and the proposed guidance is fine as it is.

"Basically, I'm pleased with it," Gellis says. "We have set up a conflicts of interest committee, and we have specific questions on our form related to conflicts of interest."

If the government were to mandate specific procedures it would create more problems, Gellis adds.

First, it's difficult to convince faculty to buy-in and comply with procedures that may not be a good fit for a particular institution, and secondly, it makes the process a rigid, one size fits all.

"That's always the problem with human subject regulations, because they're designed for clinical research, and so those doing behavioral and social science research say this doesn't fit what they do," Gellis explains.

The guidance as it now is written allows institutions to develop procedures that are best for their particular institution, while simultaneously giving IRBs and institutions a consensus of best practices, she says.

Although the guidance creates no new regulations or requirements it will and already is having an impact on how academic institutions handle financial conflicts of interest and research, says **Kathy McClelland**, research compliance director of Stanford (CA) University.

"Academic institutions will change policies with regard to the guidance," McClelland says.

Stanford already has a strong program for protecting against financial conflicts of interest, and it continues to be improved, McClelland says.

In the early 1980s, the university implemented conflict of financial interest policy into the IRB

system, and within the past five years, the policy has been revamped according to federal guidance, McClelland adds. "We'll do so with this guidance, as well."

Also, Stanford has a strong conflict of interest committee that keeps in close communication with the IRB. The IRB's protocol form includes questions about conflicts of interest, and this form is sent to the conflict of interest committee when an investigator indicates any sort of conflict of interest, McClelland says. **(See sample questions from Stanford's protocol application form, p. 67.)**

While the committee assesses the conflict of interest, the IRB goes forward with assessing the protocol's risks and benefits and informed consent form. However, there have been instances when the conflicts of interest committee has informed the IRB that a particular protocol has potential conflicts of interest that make it unsuitable for Stanford, McClelland says.

[Editor's note: The proposed guidance, called "Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subjects Protection," may be viewed on the Internet at http://www.fda/gov/OHRMS/DOCKETS/98fr/03-7691.html.] ■

SPOTLIGHT ON COMPLIANCE

False advertising laws apply in clinical arena

Advertising, incentives must follow rules

By **J. Mark Waxman**, JD
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One of the challenges in clinical trial operations is to recruit patients to participate. The Food and Drug Administration (FDA) notes that recruitment "methods and material" also should be reviewed as a part of the IRB oversight function.[1]

Implementing this guidance will require IRBs to review advertising materials, as well as the payment of recruitment fees whether to the investigator, the patient's primary care physician, or directly to patients.

The FDA points out that direct-to-participant advertising, such as newspaper, radio, and flyers, is not an objectionable practice. Instead, these efforts are perceived as part of the informed consent process, as well as subject selection. In that context, these advertisements would be subject to IRB review, which, in addition to ensuring factual accuracy and consistency with an approved protocol, would consider whether there is a perception created leading to undue influence. The key elements of concern would be any express or implied representation of a favorable outcome from the trial or the ability to receive some other benefit inconsistent with or beyond what is specifically set forth in an approved protocol. [Where only protocol comparison is necessary, expedited review can be appropriate. See 21 CFR§56.110 (b)(2).] An advertising review also would focus on ensuring that:

- No express or implied claims that the drug or device being tested is safe or effective for the purposes being tested, or that the item involved is superior (or even equivalent) to any comparable item. In the eyes of the FDA, that representation would be both misleading and most importantly, a violation of regulations which specifically prohibit promotion of investigational drugs;[2]
- There is not a representation that the drug or device is not investigational. For example, an advertisement which suggested the trial was or would lead to a new treatment, without making its investigational nature clear, would be misleading;
- There should not be a promise of "free" drug supplies or devices or "free treatments" if the true facts are simply that there will not be a charge for taking part in the investigation. Indeed, the use of inducements in the form of free treatments or free devices would have to be scrutinized carefully to ensure issues of fraud and abuse do not arise where Medicare or Medicaid patients may be involved. Section 1128A (a)(5) of the Social Security Act addresses a series of circumstances in which such inducements are prohibited.

What can you say?

The FDA suggest the following factually accurate information would be acceptable:

- the name and address of the investigator, entity, and facility involved;
- the condition under study and/or the purpose of the research;
- eligibility criteria;

• participation benefits;
• the commitments required of study participants;
• contact information.

Advertising for subjects is not the same as communications to third parties about trials. For example, an investigators' brochure is not required to receive IRB approval, although its contents may be useful information for IRB members and staff. Objective and basic information listings of clinical trials being conducted by an institution also would not require IRB approval.

The FDA further has acknowledged that communications not require review. This category includes not only doctor-to-doctor communications, including those soliciting for trial subjects, but also publicity intended for third parties such as investors, which might appear in the trade press or even as advertisements in the financial pages of newspapers.

What can you give?

Payments for participation are recruitment incentives. They may be particularly desirable where benefits are nonexistent (e.g., many trial participants will receive a placebo). The IRB must be informed of such benefits and approve them to ensure they are neither "coercive" or present "undue influence." (21 CFR §50.20.) This means that all information regarding payment should be approved as a part of the approval of the informed consent document. The belief is that material payments may coerce or influence those without means to be to participate in a particular clinical trial. It is generally understood, however, that a payment designed to compensate at a reasonable level for the time commitments required — i.e., as compensation for tests or other participatory activities — can be appropriate. An incentive or bonus for completing the study may also be approved, although the FDA has indicated its view that the entire payment should not be contingent upon completion. This might itself be coercive of an inappropriate continuation in a trial of a participant.

As previously noted, however, where Medicare or Medicaid patients are involved, special concerns exist with respect to participation incentives.

Although the Office of the Inspector General (OIG) has the use of incentives to further clinical trial participation under review, Section 1128A (a)(5) of the Social Security Act ("1128A") prohibits the offer or transfer of "remuneration" to a Medicare or Medicaid beneficiary that the person "knows or should know" is likely to influence selection of a provider or supplier of Medicare or Medicaid payable items. A strict interpretation of this provision would mean a cash or noncash gift (in excess of $50 annually per patient) or free goods in connection with a clinical trial where the beneficiary will also receive routine Medicare services may run afoul of the prohibition. And, as the OIG has noted, there is no statutory exception for valuable gifts (e.g., free medications) based upon a beneficiary's medical condition or its severity. **(For more information, see OIG special advisory bulletin "Offering Gifts and Other Inducements to Beneficiaries," *IRB Advisor,* August 2002.)**

Recruitment fees to practitioners

Other methods to enhance patient recruitment would be to create financial incentives for the investigators themselves. While varying approaches exist, these incentives could take the form of a per-patient payment or a fixed fee when a minimum or desired enrollment level is met. Either example can create a potential or perceived conflict of interest. As noted by the America Medical Association (AMA), it is unethical to have a conflict of interest arising from payments a researcher might receive which exceed remuneration commensurate with the efforts for the researcher on behalf of the sponsor.[3] Therefore, compensation should be at fair-market value and not vary according to the volume of subjects enrolled by the physician receiving the payments. The AMA goes on to note that the nature and source of funding and financial incentives to investigators "must be disclosed . . . as part of the informed consent process."[4]

The foregoing suggests that an appropriate approach to payments to investigators would be similar to that applied to other areas in which payments are made to physicians for other than direct patient services, most notably the so-called Stark Law and its exceptions. Such approaches focus on documenting both the efforts made and its value. This would include the costs to be incurred for indirect overhead expenses as well as pure time and effort. It also is recommended the amounts involved by established in advance, and records be kept of progress along a budgeted path along the way.

A second variant on payments to obtain trial participants would be a payment to a physician for referring a patient to the trial or the investigator. Payments to another provider to refer study participants are both unethical,[5] and likely to violate

state (and federal where appropriate) laws prohibiting payments in return for referrals.

References

1. FDA Information Sheets, Guidance for IRBs and Clinical Investigators, 1998 Update. *See also* IRB requirements with respect to protect participant rights and welfare, 21 CFR§§56.109, 109, 111.
2. 21 CFR§§312.7, 812.7.
3. AMA Opinion E-8.031. *Conflicts of Interest: Biomedical Research.*
4. AMA Opinion E-8.0315. *Managing Conflicts of Interest in the Conduct of Clinical Trials.*
5. AMA Opinion E-6.03. *Fee Splitting: Referrals to Health Care Facilities.* ■

IRBs' lay members want more education, respect

Nonscientist members are committed

Nonaffiliated and nonscientist members of IRBs — the so-called "lay" or "community" members — say they need more introductory education and ongoing training to better meet the challenges of their roles.

That's the message from a survey of nonaffiliated and nonscientist members from research institutions across the country conducted by **Sohini Sengupta**, PhD, MPH, assistant professor in the department of social medicine at the University of North Carolina, Chapel Hill, and Bernard Lo, MD, professor of medicine and director of the Program in Medical Ethics at the University of California at San Francisco. An article on Sengupta and Lo's research, conducted in 2000, was published in the February 2003 issue of *Academic Medicine*.

Sengupta says that while the 32 members interviewed for the survey had generally positive experiences, they did report what they described as instances of intimidation and disrespect from the scientist IRB members.

Still, she says, the group was notable for its strong sense of commitment to the cause of human subjects protection. She notes that the mean tenure on the board was more than eight years.

"That gives you some idea that these are committed individuals," Sengupta says. "One of the main reasons they wanted to be on the IRB was to represent human subjects. They wanted to give a voice to the community of human subjects at large."

A highly educated group

Sengupta and Lo chose their interview subjects from IRBs at public institutions that received more than $25 million in funding from the National Institutes of Health during fiscal year 1999. Further restrictions included only surveying members who had served more than six months on IRBs that were medically focused.

The authors contacted more than 20 IRBs, drawn from different geographical regions, and eventually were given access to 32 lay members from a total of 11 boards. They conducted telephone interviews, asking both open- and close-ended questions regarding the types of education members had received, their interactions with other IRB members and recommendations for improvement.

Nonscientist members include lawyers, ethicists, cancer survivors and religious leaders who serve on the IRBs. Nonaffiliated members might be scientists, but are not affiliated with or related to anyone affiliated with the IRB's parent institution.

Sengupta says the lay members she and Lo interviewed are a highly educated group; 23 of them, or 72%, held graduate or professional degrees. Three were lawyers, six had PhDs, and one was a dentist.

"One can argue that this is a limitation of the lay members," she says. "Are they really representing the community in this sense?"

Several told her that they had become interested in serving on an IRB because of personal experience with human subjects research.

"A lot of people brought in their experiences — one might be a mother whose son or daughter participated in clinical trials," Sengupta says. "And this is the reason they wanted to be on the IRB, because they didn't like the way their son or daughter was shuttled through the medical system, within this context of research."

She says that while 94% of participants report positive experiences working with the scientist members of their IRBs, 88% say they occasionally had experienced disrespect or intimidation serving on the boards.

One member, who had a background in research, but was considered a nonscientist, complains that nonprofessional members of his panel never participated in the discussions. He describes what happened when he once offered comments regarding a

drug being studied.

"Now it turns out that I know something about Drug A, and I simply asked the question, 'Has anybody looked into whether the two adverse events were related to noncompliance?'" he recalled. "They kind of look at you like you just landed from Krypton. And the conversation goes on."

Some say they thought they were merely tolerated on the IRBs because their presence was federally mandated.

But most believe they make real contributions to the work of the boards, particularly in the area of improving the clarity and readability of consent forms, Sengupta says.

More education needed

In the survey, members say they need more initial training and continuing education to prepare for their work on the IRBs.

Out of the 32 members surveyed, 23 (72%) say they were given printed information, such as a manual or a copy of the Belmont report, in advance of attending meetings. Ten, or nearly a third, sat in on sessions to observe how the IRB worked, and only seven, or 22% , had a formal orientation period.

"That [formal orientation] could be anything from a one-hour conversation with the IRB administrator and chair to an actual half-day of going through the materials they've been presented, asking questions, etc.," Sengupta says.

Twenty-two members, or 69%, had attended the annual conference of Public Responsibility in Medicine and Research (PRIM&R). One member says the conference provided a chance to talk to other nonaffiliated and nonscientist members and find support.

Sengupta says future PRIM&R conferences could offer specific workshops for new lay members, so that they could learn from each other, as well as from experienced nonscientist and nonaffiliated members. Recommendations identified in the study include:

- **Better education.** Members say they want more training in ethics and other research issues, not just for lay members, but for everyone on the board.
- **More lay members.** Some suggested increasing the number of nonaffiliated or nonscientist members. "On some of the IRBs I spoke to, it sounded like one person was taking on the role of nonscientist and nonaffiliated member," Sengupta says. "It really should be separated."
- **More involvement.** Lay members should have the opportunity to participate fully in the process, without being assigned tasks that they lack the education or specialized training to complete.
- **Better leadership.** Sengupta says that ultimately, the IRB's leadership is responsible for how lay members are seen by other board members.

"I think the chairs have a responsibility to change the culture of the IRBs, so lay members aren't feeling like they're not respected, or they're just an editor for consent forms," she says.

"I don't necessarily think [IRB chairs] would be happy to hear that — they already think they have too much to do. But the chair is one of the scientist members, and the culture of the group will only change if there's a change in the way the scientist members respond to the lay members."

Sengupta says that in the future, she'd like to examine the work of private IRBs, as well as replicating this study with IRBs that focus more on behavioral science and humanities.

Reference

1. Sengupta, S, Lo, B. The roles and experiences of nonaffiliated and nonscientist members of institutional review boards. *Acad Med* 2003; 78(2):212-8. ■

COMING IN FUTURE MONTHS

- Informed consent waivers for emergency department research?
- A guide to selecting research educational materials and textbooks
- HIPAA headaches discussed by IRBs
- Ethics education in the graduate biosciences

CE/CME objectives

The 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;
- describe the regulatory qualifications regarding human subject research;
- comply with the necessary educational requirements regarding informed consent and human subject research;
- apply the necessary safeguards for patient recruitment, follow-up, and reporting of findings for human subject research;
- explain the potential for conflict of financial interests involving human subject research;
- discuss reporting adverse events during research. ■

CE/CME *questions*

Physicians and nurses participate in this continuing medical education program by reading the article, using the provided references for further research, and studying the questions at the end of the issue.

Participants should select what they believe to be the correct answers, then refer to the list of correct answers to test their knowledge. To clarify confusion surrounding any questions answered incorrectly, please consult the source material. **The semester ends with this issue.** You must complete the evaluation form provided and return it in the reply envelope provided in order to receive a certificate of completion. When your evaluation is received, a certificate will be mailed to you.

21. Which of the following is generally considered an unacceptable way to handle the recruitment of college student subjects for faculty research projects?
A. Offering only the students who volunteer to be research subjects extra credit in a particular class or program.
B. Taking away extra credit from students who volunteer to be research subjects but then don't show up to participate.
C. Offering students a choice between 1½ hours of participation as a research subject or writing a 10-page paper.
D. All of the above

22. The Department of Health and Human Services on March 31, 2003, issued new proposed regulations regarding institutions, IRBs, and the issue of financial conflicts of interest and research.
A. True
B. False

23. Advertisements may contain:
A. Eligibility requirements
B. Participation benefits
C. Contact information
D. All of the above

24. In a survey of lay members of IRBs, what percentage of members had a formal orientation period before beginning work on the board?
A. 9%
B. 22%
C. 64%
D. 84%

Answer key: 21-D; 22-A; 23-D; 24-B

Schulman Associates
Institutional Review Board, Inc.

REQUEST FOR ALTERATION OR WAIVER OF AUTHORIZATION

If requesting an alteration or waiver of authorization under the HIPAA Privacy Rule*, you must provide **complete and detailed responses** to the following questions:

1. Does the use or disclosure of Protected Health Information ("PHI") involve more than a minimal risk to the privacy of individuals?
   [ ] Yes [ ] No

2. If the answer to Question No. 1 is "No":
   a. Describe your plan to protect all identifiers from improper use and/or disclosure.
   b. Describe your plans to destroy identifiers (or links) at the earliest possible time and state when this will occur. (If necessary, justify why identifiers will not be destroyed at the earliest possible time.)
   c. Describe the steps you have taken to assure that the PHI will not be reused or disclosed to any other person or entity (except as required by law, for authorized oversight of the research study or for other research for which the use or disclosure of PHI would be permitted by law).

3. Why is it not practicable to conduct this research without the alteration or waiver of authorization?

4. Why is it not practicable to conduct this research without access to and use of PHI?

5. Under the federal regulations, investigators may obtain only the minimum necessary PHI to achieve the goals of the research. Please explain why the PHI requested is the minimum necessary to achieve the goals of this research.

*For additional information go to: www.hhs.gov/ocr/hipaa

Source: Schulman Associates Institutional Review Board, Cincinnati.