IRB ADVISOR

Your Practical Guide To Institutional Review Board Management

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IN THIS ISSUE

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MARCH 2010
VOL. 10, NO. 3 • (pages 25-36)

Active or passive: Gaining consent from parents for student surveys

Regulations, IRBs favor obtaining active consent

When researchers want to survey underage students in school settings, it's obviously necessary to get permission from the children's parents. But exactly how that permission is best obtained has been a matter of debate.

Many researchers support a process known as "passive consent," in which parents are notified about a study and given a means to let the school or researchers know if they don't want their child to participate. If the parents do not act, consent is assumed.

According to the Office for Human Research Protections (OHRP), such a procedure does not comply with the regulatory requirements for seeking parental permission and many IRBs strongly discourage the practice. Researchers often are told to either use active consent — in which a parent must return a consent form in order for a child to participate in a study — or seek a waiver of parental permission.

In addition, the U.S. Department of Education now requires active consent for the research it funds, says **Steven B. Pokorny**, PhD, director of health promotion with the Alachua County Health Department in Gainesville, FL. Pokorny previously served as senior project director on an NCI-funded study of youth tobacco use.

But studies over the past 10 years show that requiring active consent results in significantly lower response rates.

In addition, some researchers note that active consent processes lead to under-sampling of minorities and of certain groups of at-risk children, potentially biasing studies. In most cases, they say, parents who don't return consent forms don't actively oppose their children's participation, they simply didn't see the form or didn't have time to fill it out and return it.

"The ones who return the form, they're a unique segment of the population that are on top of things," Pokorny says. "They're able to process things that come through the house. But there may be folks who are in the riskier classification for some of our research, who aren't capable of doing that, for various reasons."

The situation leaves IRBs with a delicate balancing act — weighing the importance of a parent's right to decide about a child's research participation against the potential impracticability of conducting research about important youth health issues such as drug, tobacco and alcohol use.

"From the perspective of the scholar, you're clearly giving up a lot when you go to active consent," says **Ronald B. Rapoport**, PhD, a professor of government at the College of William and Mary in Williamsburg, VA. "People who are not responding tend to be of lower socioeconomic status, they're more likely to be non-white, and they're more likely to be on the school lunch program."

They are, in short, the people researchers often most want to reach, he says.

Pokorny says active consent can raise another problem — many schools won't allow research that includes it, because of the increased staff burden associated with administering it.

"Many times, if you go to a school and tell them you have an active consent requirement from your IRB, they'll shut the door on you right there," he says.

But he and others argue that it's not impossible to achieve success with active consent, if researchers are willing to be creative and to work with schools to craft a process that fits the student population being studied.

Parents 'not paying attention'

Matthew Courser, PhD, a Columbus, OH-based associate research scientist with the Pacific Institute for Research and Evaluation, set out to study risky student behaviors such as alcohol and drug use in 14 Kentucky school districts. He was able to compare the demographics and the results from two different groups of schools: Seven school districts administered his survey using active consent while seven demographically similar districts used passive consent procedures.

In each case, packets of information about the survey, including a consent form, were sent home with students about three weeks before the survey was scheduled. In an effort to boost participation in the active consent group, incentives such as gift cards or free refreshments were offered to students who returned their forms, regardless of whether their parents gave consent.

Despite the incentives, the active consent schools only averaged a 29% response rate, compared to a 79% response rate for schools assigned the passive consent procedure.

Students who participated in the study in the active consent schools were on average younger, less likely to be male and less likely to say that they had used drugs or alcohol than those in the passive consent group.

With those kinds of numbers, you'd expect

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 and at additional mailing offices.

POSTMASTER: Send address changes to ***IRB Advisor***, P.O. Box 740059, Atlanta, GA 30374.

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Editors: **Suzanne Koziatek** and **Melinda Young**.
Associate Publisher: **Coles McKagen**, (404) 262-5420 (coles.mckagen@ahcmedia.com).
Managing Editor: **Gary Evans**, (706) 310-1727, (gary.evans@ahcmedia.com).
Director of Marketing: **Schandale Kornegay**.
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Editorial Questions

Questions or comments?
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Courser to be a strong advocate for passive consent procedures. But Courser, who also serves on PIRE's IRB, says his thinking was changed by a post-study survey and focus groups he held with parents.

In the survey, he asked parents whether they remembered getting the consent form. Very few parents in either the active or passive consent arm of the study did remember getting the form, but they over-reported returning the forms.

"Parents thought if they were a good parent, they would have returned the form," Courser says. "It reinforced the growing view — and it's my own view as well — that passive consent isn't consent at all.

"When I started the project I had hoped to make the argument that IRBs are out of whack on this one and that they needed to relax," he says. "But then hearing from parents that they're not paying any attention at all — I just don't think at the moment that there's any way I can make a general sort of call to support going to passive consent and still being within the regulations."

Pokorny had a similar reaction after conducting a study on tobacco use in schools using passive consent. He says a parent called him, upset about the passive consent procedure. The parent wasn't necessarily concerned about the harm of the child participating in the study, but was angry at the assumption that he was consenting unless he took action.

Pokorny says the school district backed his team and didn't require a change in the consent procedure, but he still felt the parent's concerns should be addressed.

"One way we approached our work on this project was we didn't want to do any harm in the community in the process of trying to do good with the research," he says. "We looked at it very closely and said, can we move to more of an active consent process and how can we do it in a way that doesn't overburden our staff or the school system in trying to get that consent?"

Improving response rates

Pokorny has worked with dozens of school districts trying to craft smart approaches to active consent that produce more than the usual lackluster response rates.

He meets with school administration to see how schools get parents' signatures on other necessary documents — a report card, for example, or a statement saying they've read the student handbook. And then he tries to incorporate the research consent form into that existing process.

At one school, he inserted a consent statement into an all-inclusive school permission form that addressed items such as handbooks and students' Internet use. "We had a 90-something% return rate on the consent form and it was no additional work for them or us to do that."

He's attended school registration events, and assigned staff to stuff consent information into student packets to eliminate any potential burden and win the school districts' approval for the active consent.

Pokorny says one reason active consent has such a bad reputation is because researchers often implement it in the least effective ways possible.

"They have this notion of a standard procedure — how do you get this form to the house and back — and they send it in the mail. But I'm sorry, that's just not appropriate for some populations," he says. "Or they stick it in a kid's backpack. Well, you've never been a parent if you think that's a viable way to get something home and have a parent look at it. It's not going to happen."

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When passive consent may be the only way

IRBs must find minimal risk, no alternatives

While passive consent may not be the preferred way of obtaining parental permission to survey underage students, researchers say there will continue to be some situations in which it's the best and perhaps only practical choice.

The challenge for IRBs is identifying those situations.

The term "passive consent" does not appear in

federal regulations. The Office for Human Research Protections (OHRP) describes a process in which parental permission can be waived or altered when researchers seek to survey underage students.

In order to approve such a waiver, IRBs must find that the proposed study poses no more than minimal risk to participants, that the waiver will not adversely affect the rights and welfare of the students and that the study cannot be practicably carried out without the waiver.

Ronald B. Rapoport, PhD, a professor of government at the College of William and Mary in Williamsburg, VA, says anonymity eliminates much of the risk in a student survey.

"Certainly, if you can do it in a way that is anonymous, that is very important," he says.

In Rapoport's own research on youth obesity, responses were not anonymous — answers about eating habits and height and weight information collected separately had identifiers so they could be linked — but he says identifying information was stripped out almost immediately afterward, so that individual participants couldn't be identified.

"I think that (process) does provide significant protection," he says, noting that researchers need to be able to give the IRB the usual assurances about the security of data and how it is stored.

The other potential risk to students is in the questions themselves. Many student surveys ask about potentially sensitive information such as illegal activity, sexual activity and substance abuse.

Steven Pokorny, PhD, director of health promotion with the Alachua County Health Department in Gainesville, FL, has surveyed 40,000 students in longitudinal studies in middle and high schools.

"Some people will perceive items about sexual behavior as an exposure of risk to the child," he says. "Or even about tobacco and other drugs. There are folks who believe if you ask kids about this, you will stimulate their interest and they'll go out and want to do it. I don't buy that, but that's a concern for some people, including some parents."

He says IRB members need to think about the study from a parent's perspective.

"Is it likely that any parent could become upset about the content of the research?" he says. "If one can be confident — if you can't even think of a friend or a friend of a friend's parent who'd be upset at all by any of this — then it's probably safe (to be conducted with a waiver)."

Researchers say there are situations in which it is impracticable to use active consent in a student survey. For example, the schools themselves may require passive consent, since it is easier for them to administer.

And Rapoport says if the researcher is sampling a small population, it may not be possible to get enough responses using active consent to make any meaningful sense out of the data. This may be particularly true if a researcher is trying to reach a population such as single-parent families or lower-income families, who are harder to reach.

Matthew Courser, PhD, a Columbus, OH-based associate research scientist with the Pacific Institute for Research and Evaluation and IRB member for the institute, says that researchers who want to use passive consent should be able to show an IRB that they have created multiple avenues of communication to parents.

"I might want to see multiple mailings, trying to get hold of parents a couple of different ways," Courser says. "I'd like to see an effort to really try to engage the parents, rather than do what I and other researchers love to do, which is send out a letter and assume if you don't hear back, that they read it, understood it and really don't mind their student doing it."

Pokorny says researchers can go to parent advisory boards or PTOs to discuss the study and take questions.

"If the researcher could demonstrate that (he or she) has presented the full context of the study in that kind of setting and none of the parents thought that anyone would object, then you could feel more comfortable going with a passive mechanism." ■

Unique approach assesses social risks to participants

Developer warns it's not answer for every study

Researchers at Temple University in Philadelphia, PA, have developed a novel approach to assessing the potential social risks to participants in a research study before the study commences.

The approach, called rapid policy assessment and response (RPAR), also has been used for non-research health interventions in dealing with groups such as drug users and sex workers. It pulls together analysis of existing laws in the

study population with a rapid collection of data about how those laws are implemented on the ground, potentially affecting patients or subjects.

In a recent article in The American Journal of Bioethics, author **Scott Burris** describes its use as an assessment tool prior to an HIV prevention drug trial. Burris, JD, a professor of law at Temple, says he was hired by the HIV Prevention Trials Network (HPTN) to conduct an assessment of the social risks that might be faced by drug users in Thailand and China who were recruited to participate in a trial of the opiate addiction treatment suboxone.

The assessment confirmed what many researchers knew anecdotally — that drug users in both countries faced serious social risks. In China, drug users are often assigned to detoxification and "re-education" camps. In Thailand, they face pressure to enter treatment facilities and even the possibility of extrajudicial killings.

But the assessment also concluded that if researchers implemented thoughtful protections and coordinated with authorities, those risks might be minimized and in fact, participation in a study could actually protect participants.

Expensive approach

Burris, who has studied IRBs and has been critical of what he calls the overregulation of research, doesn't believe that this intensive RPAR approach is necessary or even preferable for most studies. For one thing, it's expensive — the process conducted for the HPTN cost about $135,000.

"I never did this as a way of saying this should be the new norm," he says. "If it did become the norm, we would be adding yet another layer of burden on our research system via the IRB.

"I did it to say that there may be situations in which the social risk question is more than usually piquant, in which there may be a real reason to be concerned. And then we don't have to speculate — on a major project that has sufficient resources, it can sometimes be possible to investigate further."

When asked by the HPTN to assess the potential risks to participants in the suboxone trial, Burris' group first reviewed the laws in each country as they pertained to injection drug users, HIV and health care. This was carried out by lawyers in both countries. Then, independent researchers at both sites looked at how those laws were actually enforced in China and Thailand, and how that enforcement could affect drug users who might be recruited to the trial.

The RPAR assessment itself was approved by IRBs at Temple and other universities where the RPAR researchers were based. Its protocol provides for ongoing monitoring, particularly collecting adverse event reports related to social risks.

The report showed that the Chinese and Thai governments imposed heavy punishments on drug users and had interfered with or opposed needle-exchange programs in the past. But it also highlighted examples of health researchers and officials who had been able to carry out projects with drug users by negotiating with police, for example, to keep them from waiting at treatment centers to arrest patients.

Added risk

Burris says one important focus of the assessment was to determine how much additional risk study participants would be exposed to, beyond the intrinsic risk of being a drug user in these cultures.

"One can say that anytime you're working with drug users in research, drug users are exposed to all sorts of social risks associated with their drug use," Burris says. "So the question that arises is would participating in the research exacerbate that risk?"

"Not surprisingly, we found that assuming that the work is done with a reasonable amount of circumspection, concern for confidentiality and appropriate consultation with authorities, we thought it was pretty unlikely that there would be a marginal addition to risk," he says. "Indeed, we found it appeared it could actually be protective in some way."

He says that the message for IRBs isn't to start requiring researchers to do the intensive assessment his group did in this trial. In fact, researchers may be able to thoroughly examine issues of social risk by a less involved process, such as a more formalized desk review of existing data.

"For IRBs, I think the question is has the researcher thought through the issues, and collected the necessary information to make a reasonably good judgment and then in fact, made a good judgment?" Burris says.

"As a general matter, IRBs will do better in assuring that the researcher has thought things through, than in trying to imagine it through

themselves," he says. "In research like ours, researchers have usually done research like this before, while IRB members typically don't have a clue — they've never been there, never dealt with drug users. You have to be cautious in substituting the IRB's judgment for that of the researchers."

Reference

1. Burris S, Davis C. Assessing social risks prior to commencement of a clinical trial: Due diligence or ethical inflation? Am J Bioeth 2009 Nov;9(11):48-54.

For more information about rapid policy assessment and response, please visit www.rpar.org. ■

High pay: When is it too much of a good thing?

High sum may actually increase vigilance

Large compensation to subjects for their participation in a study is considered a red flag by many IRBs, who worry that it could provide undue inducement to join a study without considering its risks.

But a recent study of participants' attitudes about compensation amounts suggests that large sums may actually do the opposite.[1] Subjects appeared to see them as a signal that they should examine the risks of a study more intently, says **Cynthia E. Cryder**, PhD, MS, an assistant professor of marketing at Washington University in St. Louis, MO.

"People are more vigilant when they are offered these high amounts of compensation," Cryder says. "And in one of our experiments, when we told people that their compensation amount was linked to the amount of risk in study, people were even more vigilant."

Cryder, who studies decision making, teamed with specialists in research ethics and decisional research and with a clinical researcher to look at how people infer information from incentives that are offered to them in a study.

They used an online survey to ask participants to evaluate a "health and cognition study" involving the use of transcranial magnetic stimulation (TMS), a procedure that uses magnetic fields to stimulate nerve cells in the brain. TMS was chosen because it was more intrusive than many common procedures and was newer, with more uncertainty about risks.

One group asked to evaluate the study was told the compensation for participation was $25, while another group was told it would be $1,000. After reading about the study, participants were asked to rate the riskiness, first by using a Likert scale (1-7, with 1 being "not at all risky" and 7 being "very risky") and then by comparing the relative risk of the procedure to other activities such as flying in a plane, talking on a cell phone or obtaining a body piercing.

Participants rated the riskiness of the TMS procedure to be significantly higher when they believed the compensation was $1,000 than when it was presented as $25.

More vigilance

In a second experiment, participants actually believed they were being recruited for either the TMS study or for a second study that would require a simple blood draw, Cryder says. For each type of procedure, participants were offered $25, $100, or $1,000 as compensation.

After looking at a Web page showing the main study details, participants could navigate through other pages explaining the study further, including details of risks, contraindications and side effects. At any point in the session, the participant could stop viewing study details by clicking a button marked "make a decision about participating."

For both the TMS study and the blood draw study, participants clicked more pages for information and spent more time viewing study information when the compensation amounts were larger. In the case of the TMS study, for example, participants spent 3½ minutes viewing information when compensation was $1,000, compared to one minute when it was only $25.

Higher compensation specifically increased the likelihood that participants would read the information about contraindications.

While participants viewed more information in the TMS study than in the blood draw study, they were more likely to agree to participate in the blood draw, which Cryder and her colleagues believes shows increased vigilance because of the higher compensation, as opposed to simply increased interest.

In a third experiment, which only looked at the TMS study, participants were told that the compensation amount (either $25 or $1,000) was

"appropriate" for the risk level of the study. In that experiment, participants were even more likely to see the higher compensated study as more risky.

Socioeconomic status

Cryder says it's significant that this result held across socioeconomic lines. Two populations were recruited, one from the Web site of the New York Times science blog and one from various Pittsburgh neighborhoods using a mobile lab with Internet access.

"One of the biggest things we were looking for was (the effect of) socioeconomic status," Cryder says. "One of the big concerns with high levels of compensation is that it is especially dangerous for poor people."

But she says the results showed that both groups behaved similarly in their assessments of the risks of the studies.

Cryder says IRBs can glean two important points from the study:

-Don't worry so much about high compensation. "I don't know if IRBs should encourage high compensation, necessarily, but they should be less worried about it, for sure," Cryder says. "Because people are more vigilant when they are offered these high amounts of compensation."

-Subjects may assume that low compensation equals low risk, even if that's not necessarily true.

"If IRBs allow compensation to [equal] risk, they should let participants know," Cryder says. "If not, they should also let participants know that the amount of money they are being offered is not related to the risk in the study. Because participants naturally assume otherwise, that's what our study showed."

Despite her study's findings, Cryder doesn't think the issue of whether to allow high compensation for research participation will be resolved anytime soon.

"There are still differences of opinion among the experts, and I'm sure there are differences of opinion among IRBs," she says. "I think it is controversial and I think it will continue to be controversial."

Reference

1. Cryder CE, London AJ, Volpp, KG, et al. Informative inducement: Study payment as a signal of risk. *Soc Sci Med* 2009 (Epub). ■

IRB Experts Q&A

Controversy: Informed consent and cluster-randomized trials

Two takes on a thorny issue

In this question-and-answer session, **Mark Schreiner**, MD, chair of the Committees for the Protection of Human Subjects (IRB) at the Children's Hospital of Philadelphia (CHOP) and an associate professor of anesthesia in pediatrics at the University of Pennsylvania in Philadelphia, PA, discusses the issue of informed consent in cluster-randomized clinical trials.

Schreiner, who also is an editorial advisory board member of IRB Advisor, believes that regulations under the Food and Drug Administration (FDA) preclude waiving individual informed consent when cluster randomized clinical trials involve the comparison of one or more FDA-regulated drugs, devices, or biologics. His comments are in response to papers published on cluster randomized trials in the *Hastings Center Report and Pharmacoepidemiology and Drug Safety*, as well as an article on the topic in the January, 2010, issue of *IRB Advisor*.[1,2]

IRB Advisor: We have seen the email you received from **Christine Oliver**, PharmD, of the FDA's division of drug information. In response to your question about whether FDA regulations would permit a waiver from individualized informed consent in cluster randomized clinical trials involving FDA-regulated substances, she wrote to you: "You are correct that waiver of the informed consent requirement is not permitted for FDA-regulated studies. While the study may be exempt from 312, it specifically states in 312.2(b)(l)(iv) that both Parts 50 (regarding informed consent) and 56 (IRB review and approval) are applicable even for studies with approved drugs used as described in the approved labeling. Informed consent requirements cannot be waived for studies considered to be FDA-regulated except in emergency conditions (50.23) or for emergency research (50.24). For studies with approved/cleared devices used according to approval/clearance, no comparable statement requiring adherence with Parts 50 and 56 exists in the exemptions section of Part 812

(812.2.(c)), but we still consider most such studies to be FDA-regulated and therefore Parts 50 and 56 are applicable.

What is the cause of this controversy over informed consent?

Schreiner: Many people don't understand that studies of approved drugs that don't require an IND must still comply with the FDA's IRB regulations. So even when an IND is not required to study a drug that is approved, the study must still comply with Parts 50 and 56.

That's where the problem comes in: Part 50 (§50.23 and §50.24) only allows waiver of informed consent from the individual for certain types of emergencies, emergency conditions, and emergency research.

What the articles proposed was that it was okay to do a cluster randomized trial where permission was obtained from the practices, without getting individual consent from the subjects. This is okay if the intervention isn't a drug, biologic, or device regulated by the FDA and where the IRB could waive consent. For example, an IRB could waive individual informed consent for a cluster-randomized trial of two different diets to determine if there was a difference in weight loss between the two groups because the study doesn't involve any FDA-regulated test articles.

Studies of approved drugs conducted at institutions with an FWA must comply with both the common rule and FDA regulations, and that's where the snag comes in. I just don't think most people are aware that when they're studying an approved drug that they have to follow the FDA regulations, which are slightly different than the Common Rule.

IRB Advisor: So how should institutions and IRBs handle reviews of cluster randomized clinical trials?

Schreiner: First, they should determine if the intervention is regulated by the FDA. If it's not, then the IRB can decide whether or not to waive consent.

We have a number of cluster-randomized trials underway at CHOP where we've waived consent. Most are studying the impact of electronic health records on improving care. The Obama administration is very keen on getting electronic health records, but it's not so clear exactly what the individual benefits will be for that. So a number of investigators are looking at whether some of the services available in electronic health records, mainly warnings and reminders, improve care. For example, if a patient is eligible for a flu shot, the screen will flash and remind doctors to give the patient a flu shot. Some studies look at whether or not there is a difference in the percentage of kids who get what are considered the guideline practices between the doctors who receive an electronic reminder and doctors who do not. Since we have about 30 practice groups that are part of our health care network it is possible to randomize them into two groups to conduct this sort of trial.

Another example is a study to see if antibiotic usage and prescribing habits can be improved by providing electronic health record reminders and educational materials. Will it work? Physicians are very busy, and they could ignore the messages.

IRB Advisor: Why would cluster-randomized drug comparison research be that different from what you've described?

Schreiner: It is important to remember that the studies I've described are not comparing two drug treatments where the practice is randomized to prescribe drug A or drug B. In the antibiotic reminder study, the investigators are just giving doctors information. The practices are randomized to different means of receiving information; one gets the electronic health record reminders, and the others just get standard practice.

The whole point of cluster randomization is to make large scale trials feasible. The randomization is not at the level of the patients, it's the practices that are being randomized. If the intervention is not regulated by the FDA and the IRB decides it meets the requirements for waiver of consent (45 CFR 46.116(d)) then they can waive consent.

What the recent papers proposed was to randomize practices A, B, and C to give one drug, and practices D, E, and F to give another drug in order to determine which of the two commonly-prescribed treatments was better.

The cluster-randomized trial design provides an easier path by avoiding the need for consent from individuals. But since the intervention is a drug regulated by FDA, the IRB must require that the investigators obtain the consent of every individual subject.

IRB Advisor: What about your example of a cluster randomized trial looking at antibiotic prescribing habits?

Schreiner: The IRB was able to waive informed consent because the investigators were able to demonstrate that the study was minimal risk, and it wasn't practical to get informed consent from 30,000 to 50,000 children coming in for

office visits with ear infections. Clinicians will get information messages with reminders that these are antibiotics that should be first-line treatment, which is not any different from the way the insurance company says, 'These are the drugs on our approved formulary for an ear infection,' and the physician is free to read the message and prescribe based on this information or not. The other practices don't receive any reminders, just their usual update to review antibiotics.

Scientist responds to issue

Editor's note: IRB Advisor asked **James E. Sabin**, MD, director, ethics program at Harvard Pilgrim Health Care, and clinical professor in the departments of population medicine and psychiatry at Harvard Medical School in Boston, MA, to respond to Schreiner's comments about the need for individual informed consent.

IRB Advisor: Your papers on cluster-randomized trials discuss gray areas in interpreting the need for individual informed consent for the types of cluster-randomized trials you've described. Dr. Schreiner and the FDA email state there are no gray areas when the study involves comparison of drugs, biologics, or devices that are FDA-regulated. How do you respond to this point of view?

Sabin: 312.2(a) states that Part 312.2 applies to "all clinical investigation of products…" Therefore, the key question is — what is a "clinical investigation"? According to 312.3(b), a "clinical investigation" is "any use of a drug except for the use of a marketed drug in the course of medical practice."

In the form of cluster randomized trial we envisioned, the drugs were commonly used "in the course of medical practice," and were in clinical equipoise with regard to their comparative effectiveness. In the envisioned trials, one set of clusters would give preference to drug A while another set gave preference to drug B, but prescribing physicians retained the option of prescribing the non-preferred agent if, in their clinical judgment, it was preferable for a particular patient.

In contemporary practice physicians often receive memos or prompts encouraging them to choose a particular agent among the many that are in common use. In the cluster randomized trials that we were discussing, the assignment of the cluster creates the equivalent of a prompt, which the prescriber is not required to follow.

These are the conditions of ordinary medical practice. My colleagues and I concluded that in terms of 312.3(b) the kind of comparative effectiveness trial we were concerned with is not a "clinical investigation." Given that interpretation of 312.3(b), 312.2 does not apply, and, as a result, Parts 50 and 56 are also not applicable.

Even if we assumed Parts 50 and 56 to apply, the definition of "clinical investigation" remains crucial. Part 50.3(c) defines the term as follows: "any experiment…that either is subject to requirements for prior submission to the FDA…or is not subject to requirements for prior submission…but the results of which are intended to be submitted later to, or held for inspection by, the FDA as part of an application for a research or marketing permit."

The kind of comparative effectiveness studies we were discussing were not subject to prior submission, and involve no intention to obtain a marketing permit. On that basis we concluded that Part 50 would not apply even if Part 312.2(b) did.

IRB Advisor: If the federal government's new goal is to increase the number of drug comparison studies, as has been stated by the Obama Administration, do you believe the requirement of individual informed consent will have a significant impact on reaching this goal?

Sabin: If individual informed consent is required for the kinds of cluster randomized trials we envisioned it will drastically reduce the potential for drug comparison studies. Requiring individual informed consent for every drug comparison study would effectively kill the Obama Administration's comparative effectiveness initiative.

IRB Advisor: Do you believe there will continue to be a public debate over this issue, and how might it proceed?

Sabin: There will and should be public debate. FDA and OHRP regulations were not constructed with comparative effectiveness studies of commonly used products and common medical practices in mind. Debate should proceed by first asking what consensus can be reached about what is right from the perspectives of clinical practice, public policy, and medical ethics. When we're clear on these questions we should look at the regulations. Do they promote the ethically desirable outcomes? If so, fine. If not, change them.

References

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IRBs develop successful training on tight budgets

Internet has varied and useful resources

Nationwide, research institutions are cutting costs in response to the economic downturn. Funding for education and training has been one area hit fairly hard, and this made it a challenge for IRB offices to meet their educational demands.

But this doesn't mean they should give up on providing quality educational programs. Instead, they should view their educational budget cuts as an opportunity to be creative and develop a low-cost training program, experts suggest.

There are a variety of ways IRB directors can provide educational materials and programs even while staying within the smallest of budgets. Although, it does require time and effort to ensure that free educational materials are up-to-date and accurate, says **Megan Kasimatis Singleton**, JD, associate director of education and training at the University of Pennsylvania in Philadelphia, PA.

Two low-budget ways to develop training programs are finding and using free online research ethics training information and tapping into your own IRB members' expertise, Singleton suggests.

A chief benefit of using the Internet is that it can maximize an IRB's available resources, whether these are significant or nonexistent, says **Brenda L. Ruotolo**, CIP, associate director of the IRB office at Columbia University in New York, NY. Ruotolo and Singleton spoke about shoestring budget training programs at the 2009 PRIM&R Advancing Ethical Research Conference, held Nov. 14-16, 2009, in Nashville, TN.

"For some smaller institutions that are undergoing a hard time and really have no educational budgets, they could rely on Web sites that offer free educational materials," Ruotolo says.

Other research institutions could stretch their existing educational dollars by supplementing their own materials with free information, she adds.

"The point is to avoid re-inventing the wheel," Ruotolo says. "I think whether someone is relying entirely on using online materials or resources or is using it as a starting point to customize their program, the Internet is valuable."

Singleton and Ruotolo offer these additional suggestions for forming and maintaining an education and training program on a low budget:

• **Find affordable or free online training programs:** There are online tutorials available, including the widely-used CITI program, Singleton says.

"We use CITI to satisfy our core human subjects training requirements," she says. "Sometimes it's nice to have a core training program managed by an outside entity so when things change the program can be updated automatically without it being the responsibility of your institution."

CITI's fees are nominal and, for some institutions, might be more cost-effective than developing one in-house, she adds.

However, there are other options, including Web sites that provide education for free.

One of these is at the National Institutes of Health (NIH) Web site, which has human subjects training curriculum available at no cost.

There also are Web sites that provide education on particular subjects, and these could be used to supplement a core program, Ruotolo suggests.

For example, here are a few Web sites that Ruotolo has found particularly interesting and useful:

- The University of Michigan's Informed Consent Workshop at http://www.med.umich.edu/bioethics/workshop;

- Dana Farber's Considerations for Clinical Trial Participation at http://www.dana-farber.org/res/clinical/default.html;

- The University of Minnesota's Informed Consent tutorial at http://www.research.umn.edu/consent;

- The McMaster Carr tutorial at http://www.mcmaster.ca/ors/ethics/faculty_tutorial.htm.

NIH also has supported a Web site available for researchers. It answers their questions about research conduct and ethics and is available at http://www.4researchers.org/.

This site is useful when the main IRB training program is designed to target research coordinators and might not have information principal investigators (PIs) often need to know about research design, Singleton says.

• **Plan how free resources will be used within the greater training program**: "You could get lost on the Internet, both in time and in gathering information," Ruotolo notes. "We suggest you consider whether your online training will be the entire program or only part of a program."

Also, IRB directors should decide whether they'll require staff and IRB members to take the training or just suggest these resources for review, she adds.

If the education is required then it might be best to use a tutorial that provides a completion certificate or that has a post-tutorial quiz that can be downloaded, Ruotolo says.

"You need to decide whether you want people to click through and review the materials or pass a test at the end," she says.

• Network to find good ideas: "We've looked for opportunities to get feedback from other people about Web sites they've used that are reliable and have helped their own institutions," Singleton says.

The IRB Forum, available at www.irbforum.org, is a good place for networking, she adds.

Joining the forum is free and users can ask questions that IRB peers will answer.

Through networking, an IRB director might discover that someone else has developed and is willing to share the very same type of educational tool that he or she had intended to create from scratch, Singleton notes.

"There are people who've spent a lot of time and effort into developing really valuable presentations," she says. "You should network and collaborate as much as possible."

• **Share Webinars:** "You could co-host a Webinar, inviting an audience to attend," Singleton says.

If the IRB office could share the costs of the Webinar with another department at the institution, then staff from both sites could benefit from the educational presentation at half the cost.

"When we did a Webinar, we used a conference room seating 25-30 people, showed them an interactive slide show with an instructor talking to the group," Singleton says. "For departments with limited budgets, you could split the costs across several departments."

• **Thoroughly research online educational material**: There are two areas of caution when using free material online, Ruotolo notes.

First, IRB directors need to make certain the information provided is accurate, institutionally-relevant, and up-to-date.

"You have to make sure you agree with the content," Ruotolo says. "Just because it's an informed consent tutorial doesn't mean that it reflects how those procedures are handled at your institution."

Secondly, IRB directors should check the site regularly to make certain it hasn't closed or changed.

"There's no guarantee a site that's here today will be here tomorrow," Ruotolo says. "You need periodic evaluation."

Also, some institutions provide free access to online educational materials, but they still have

CNE/CME Objectives

The CNE/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

- Video vignettes can enhance IC process
- Simplify IRB forms following expert guidelines
- Research compliance database improves project management
- New online IRB training unveiled
- IRBs, schizophrenia researchers need to communicate better

CNE/CME *questions*

9 Passive consent is recognized in the federal guidelines as the preferred method for gaining permission from parents for student research.
A. true
B. false

10. When offered a large compensation for participation in a study, subjects:
A. Gauged the study to have a higher risk
B. Spent less time viewing risks, contraindications and other details about a study
C. Both of the above
D. None of the above

11. Which of the following is a good strategy to use when developing an educational and training program with little to no budget?
A. Network with other IRB offices to find free resources
B. Share the cost of a Webinar with other departments at the institution
C. Use free online offerings provided by other research organizations
D. All of the above

12. In which circumstances does the FDA regulation, Part 50 (§50.23 and §50.24) allow waiver of individual informed consent?
A. In the case of the standard treatment arm of a placebo-controlled clinical trial
B. For certain types of emergencies, emergency conditions, and emergency research
C. For research involving treatments that have been marketed for at least a decade
D. All of the above

Answers: 9. B; 10. A; 11. D; 12. B.

copyrights on the materials, so anyone using them might need to seek permission for adapting the materials to their own use, Singleton says.

Sometimes, it's best to be cautious and use the most direct sources in online information.

For example, if an IRB director chooses to educate people about federal regulations and statutes, then the best solution is to send them to the actual federal wording, which can be found at the agency's Web sites, Ruotolo suggests. ■