IRB ADVISOR

Your Practical Guide To Institutional Review Board Management

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IN THIS ISSUE

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Use of metrics help IRBs improve operations with laser-like efficiency

Staffing vacancy, turnover reduced

IRB professionals might not have gotten into the business of protecting human subjects because of their love for mathematics and statistics. But many now are finding that tracking data and analyzing numbers helps them do their job better.

Also, IRB directors and research administrators are implementing quality improvement projects with a more precise focus and efficiency because of the metrics they've collected.

For instance, one research institution used metrics to improve its staff retention.

"In 2006, we had a 36% vacancy rate and 50% staff turnover rate," says **Joseph O. Schmelz**, PhD, CIP, FAAN, director of research regulatory programs at the University of Texas Health Science Center in San Antonio, TX.

After reviewing staffing metrics, the institution implemented changes that have resulted in a complete turnaround: "We really haven't had any vacancies or any turnover in the last two years," Schmelz says. *(See story on staff retention project, p. 39.)*

The office also used metrics to increase efficiency in the IRB approval, says **Dawn Lantero**, PhD, research subject advocate at the University of Texas Health Science Center.

The IRB used metrics to define protocol complexity and send those eligible for an expedited review to a newly-hired expedited reviewer. This resulted in a big decrease in the submission to approval time for all studies. It dropped from 120 days in 2006 to 88 days in 2009 for studies requiring a full review; the time spent on expedited studies decreased from 70 days in 2006 to 15 days in 2009.[1]

The data also helped the institution create a new, grant-funded position of research subject advocate.

"We had to decide what would be the best activities for the research subject advocate to do, so Dr. Janice Longfield and I came up with simple

metrics and data to collect," Lantero says.

"For instance, in our grant it's important for us to be working with our affiliates, and my role is to be accessible to anyone who contacts me," she says.

Lantero uses metrics to help shape her role and schedule her time efficiently so she is available when people most needed her and so she would address the most appropriate issues, rather than issues that were better handled elsewhere.

Metrics also have proven useful for scheduling continuing reviews and maintaining a quick IRB review turnaround time, according to another IRB office director.

"We use a monthly project status report to track when expirations are happening," says **Mindy Reeter,** BS, CIP, director of the office of human research oversight, University of Illinois, College of Medicine at Peoria, IL.

The IRB's electronic system sends out 30-day and 60-day automatic email reminders. But the IRB office tracks these data to see whether a renewal period falls just after a board meeting.

"So we're able to help those people realize their expirations are happening off synch with the IRB meeting calendar," Reeter says.

Before the office collected data on project expirations, they would discover these timing conflicts right before a meeting, giving them little time to adjust the schedule. Now the IRB office and researchers can avoid deadline conflicts, she adds.

The IRB also has used metrics to better schedule staff time and deadlines. Workload is identified precisely to more accurately gauge the time required for a meaningful review.[2]

Metrics also can be used to show an institution how its IRB office is performing.

"It's hard to measure success, but the metrics do capture the types of activities that are ongoing in a human research subject program," Schmelz says. "Having those data presented as Dawn does for us is important for getting a sense of what happens outside of IRB committee meetings."

The University of Illinois IRB office collects data with assistance from IRBNet, an electronics solution company, and can compare its efficiency and activities to national standards.

For instance, the office found that it handles more protocols than the average member of the Association for the Accreditation of Human Research Protection Programs (AAHRPP), but has a more efficient convened and expedited review process.

"It's good to know we're working on a level comparable to AAHRPP-accredited institutions," Reeter says. "Our turnaround times are comparable."

The IRB office's average time to reach an expedited review decision is 14 days, while the average time to a decision for a convened review is 25 days.

Since the office began collecting metrics on how

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long the board took to reach a decision, there have been fewer complaints about delays from principal investigators, Reeter notes.

"The fact that it's being measured has meant that we work to get everything done quickly," she adds. "We don't let items sit in the queue, and our office work is improved because we want to improve our numbers."

When IRB offices collect metrics and see reports about their performances they can maintain a continuous quality improvement environment, Reeter notes.

Without data, an IRB office's chief performance feedback might come from an audit by the Food and Drug Administration.

"You never get a good idea of how you're doing until the FDA shows up on your doorstep," Reeter says. "With these monthly reports we keep a finger on the pulse of what's happening."

Electronic data collection systems are easier for this purpose, but they're not necessary for collecting metrics.

"My method of collecting metrics was to use a spreadsheet, and anytime someone contacts me or I self-reference an issue, I write specific descriptors," Lantero says. "Our goal is to get an electronic database so that anyone in our affiliate sites can log into the database and send information to others who have access to the database."

For example, Lantero might be asked a question about whether a particular research staff member is approved to do specific study activities. Lantero can access data on education and training for particular employees and find a quick answer. An electronic database would make it even easier to find this kind of information, she adds.

"In our system, the IRB office staff has created unique metrics for the parts of the program they're involved in," Schmelz says. "We all work together to make improvements based on the information

Improve IRB staffing issues following this good example

Reduce turnover rate

When internal job mobility is stagnated, it can result in high staff turnover rates — a problem no IRB wants to experience.

The solution is to collect data on what an office's staffing issues are and target a solution to meet that specific challenge.

"Four years ago our IRB office had a flat, stovepipe type of organizational structure, and all coordinators in the office were operating under a single job description, says **Joseph O. Schmelz**, PhD, CIP, FAAN, director of research regulatory programs at the University of Texas Health Science Center in San Antonio, TX.

"Among the many changes we made was to create three levels of job descriptions that started from basic coordinator and moved through intermediate and then a senior position," he says. "We created a career ladder because we had so many coordinators with varying levels of experience and background."

The goal was to stabilize a hiring environment in 2006 which more than one-third of staff positions were unfilled and half of the staff had left within one year.

Since the changes were made, the staffing situation has dramatically improved, with no vacancies or turnover in the past two years, Schmelz says.

"The career track recognized expertise, training, and background," Schmelz says. "As soon as we began to reward employees with a better position and salary for staying in the office and becoming experts in the area of IRB review, we saw the number of coordinators sitting for the CIP exam going up."

Employees now work together to improve the office's overall quality.

"With that career ladder we grouped those employees into teams to try to prove the efficiency of the office processes, and we assigned various levels of experience to the team," he says.

Then they used metrics to measure quality performance, and each team reviewed processes and established quality indicators to measure efficiency and quality, he says.

"They reported those findings in their staff meetings to show what they were finding in turnaround time, errors, omissions, and other issues," Schmelz explains. "Each team reported on quality indicators, and we discussed ways to improve the program."

These efforts have resulted in multiple improvements in the office, he adds.

"It has fostered an environment where staff sees that they'll be rewarded for improving their expertise, and it showed them that they can stay in the office as a career and not just a job," Schmelz says.

the metrics give us."

IRB employees define the metrics, make changes, and present information to Schmelz.

"We organized the office last year and are moving toward a completely electronic system," he adds. "These metrics allow us to evaluate whether the electronic system is improving our program or giving us new problems."

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IRB finds solutions to roadblocks in protocol submission process

Prevent incomplete, flawed applications

IRB offices routinely handle protocol submissions that are incomplete or flawed in other fundamental ways. These problems cause roadblocks that slow down the IRB approval process and frustrate investigators and IRB staff alike.

"Basically, we very often see protocols submitted that aren't complete or where there are problems with initial submission," says **Donna B. Konradi**, PhD, RN, CNE, chair of the IRB at the University of Indianapolis and an associate professor in the School of Nursing at the University of Indianapolis in Indianapolis, IN.

"Every time there's a problem, the IRB has to contact the investigator, and these problems have to be fixed," she adds.

This becomes a large time investment, slowing down the research process.

The solution is to anticipate the likely culprits and devise policies and process changes to prevent them from occurring.

"So our IRB had many discussions, and we talked about some of the most common problems," Konradi says. "We thought if we could put those problems out there and let our research community become aware of what the problems are, then that knowledge is very powerful, and maybe they could go through these and fix them."

The first step is to collect data about the most common errors and problems that result in stalls in the IRB approval process.

"We looked at a year and a half of submissions and identified the things that held up these protocols in the submission process, especially those that take the longest amount of time," Konradi says. "Then we put them into 10 categories."

These 10 categories of problems that result in stalls during the IRB submission process were reported to researchers and their staffs, along with potential solutions.

Researchers and faculty reported finding these very helpful, Konradi says.

Overall, the protocol submissions have improved since this solution was put in place, although some of that was related to the campus community becoming more sophisticated as researchers, she adds.

Several of the common problems involve how the protocol is completed — the nuts and bolts details typed into the electronic form. These are among the most common of the mistakes that result in stalled submissions. Others relate to omissions of pertinent information, often due to investigator's lack of knowledge about what's required. *(See story on missing waivers and insufficient descriptions, p. 41.)*

Half of the categories include policies, data security, scientific design, research team qualifications, and links or inclusion of actual documents shown to research subjects.

Developing the list of common submission problems was not time consuming because many of these items had been discussed frequently at IRB meetings, Konradi says.

"We talked about the same problems over and over again," Konradi says. "When you see the same problem for the fourth time in a given month it gets very weary."

Also, researchers often complained about the IRB review process being so slow.

"So we opened up a dialogue and shared information and resources to create better common understandings," Konradi says.

Here are some of the most common IRB application problems and potential remedies:

• **Incomplete protocol submission**: Protocols often have missing information, including descriptions of the informed consent process and specific letters of informed consent or assent.

"In some instances, perhaps an investigator is doing a study with children who are 12, and there's an informed consent signed by the parent or guardian, but there is no assent document, so something is missing," Konradi says.

Also, submissions sometimes fail to include letters of cooperation or agreement, Konradi says.

"If we're doing a study with either another business or another university or non-profit organization, then we need a letter of cooperation," she adds.

Sometimes the recruitment materials are missing, and sometimes they failed to include a validation of human subject protection training, Konradi says. "Sometimes they're missing their data collection tools, and the most commonly missed tool is for demographic information."

Or investigators say they will collect demographic information, but they never tell the IRB what that information is.

REMEDY: "We've made an updated protocol submission checklist and included many of these elements on the checklist," Konradi says. "There's a link to the checklist on the protocol submission template."

When researchers open the submission template they can move back and forth, see what's ahead and what they've already completed. With this kind of fluid movement between sections, a checklist can be useful for helping them double-check their work for omissions and errors.

• **Confusing submissions**: Sometimes protocol submissions contain grammatical errors, misspellings, and lack of precision.

"They try to sound academic or use words incorrectly, and what they say is not what they intended to say," Konradi says. "They might use too much jargon, especially in documents going out to individuals they're trying to recruit for participation."

Or the information in the submission is inaccurate and confusing.

REMEDY: "We talked with investigators about having someone else read their work to help them avoid grammar/spelling errors," Konradi says.

"Sometimes they develop these protocols as a team, and every team member turns in their stuff, and they staple it all together," she adds. "But no one looks at everything as a complete product."

The solution would be to make sure teams work together in a way that the individual contributions are complete and not fragmented when put together, she says.

• **Protocol inconsistencies:** "The places where we see the most inconsistencies are in the description of research activities, informed consent documents, recruitment materials, and letters of cooperation," Konradi says. "Sometimes what they say on one document is not consistent with what is said on the other."

For instance, a protocol might say that participation in this research will take 20 minutes. But the informed consent form says participation takes 10 minutes, she says.

"Or they'll say that participant risk is X in the protocol submission, and then they'll identify something else as risk to participants in the informed consent, or maybe say nothing about risk during the recruitment period," she adds.

Researchers have to present the same consistency throughout all documentation, and this often does not occur.

"We see this especially often when people are developing their projects over a long period of time or when they submit information from a team and haven't reconciled all documents to make sure they're consistent," Konradi says.

REMEDY: IRBs should educate research staff about the need for consistency in their protocol submission, informed consent documents, and other materials.

Sometimes, all it takes is for someone to remind research staff that this is an issue that should be resolved.

"If investigators want us to spend less time in the review process, then they should reconcile all documents before attaching them to a protocol and submitting them," Konradi says. "If investigators can fix some of these things before it goes to the IRB, then the IRB can do its work much quicker." ■

Educate investigators about waivers, research activities

IRB applications often show lack of understanding

Investigators, particularly when they are new to human subjects research, often fail to include all necessary information in their IRB applications because they are unaware of what's required.

IRBs can prevent these types of errors by educating new investigators about two of the more common types of omissions that are made, suggests **Donna B. Konradi**, PhD, RN, CNE, chair of

the IRB at the University of Indianapolis and an associate professor in the School of Nursing at the University of Indianapolis in Indianapolis, IN.

Konradi offers advice for how IRBs can handle problems with missing waivers and inadequate descriptions of research activities:

• **Incomplete or missing waivers:** New investigators might not understand what a waiver is, or they might ask for the wrong kind of waiver, Konradi says.

"They might want a waiver of documentation but ask for a waiver of informed consent instead," she adds. "Or they might have an incomplete request for a waiver, failing to provide justification for why this study is appropriate for a waiver."

REMEDY: "We gave investigators resources about waivers, information from CFR 46.117c, where they talk about the waiver of informed consent," she says.

The IRB provide resources in electronic format with links to its presentation on the topic of protocol submissions and common mistakes.

"So if they're thinking about submitting a protocol, they can download the presentation and use it with their students who are doing research," Konradi says.

Another solution was putting electronic prompts on the submission form.

"The prompt asks if they are requesting a waiver of informed consent, and another prompt asks them to provide justification," she says.

• **Insufficient description of research activities**: IRB applications often fail to describe exactly what the investigator and the research staff is going to do and how they're going to do it.

For instance, the application might include an attached data collection form, but the investigator doesn't say whether this collection form will be read to participants or left for them to fill out themselves, Konradi explains.

"If it has sensitive personal information, will they be filling it out in a group or individually?" she says. "If a person will be walking on a treadmill, then tell us specifically what speed or safety procedures you'll use."

Konradi recalls chairing one IRB review meeting in which the research submission said subjects would receive a modest shock for a nerve conduction study.

"I couldn't evaluate to what extent that would cause pain or put people at risk, so I went over there and had them give me the shock," she says. "I couldn't say the procedure would cause a little bit of discomfort unless I had something I could relate it to, and this was out of my comfort zone."

For instance, the IRB application could have said that the shock would be comparable to an electrostatic shock in wintertime.

"We have to know exactly what it is that participants will experience," Konradi explains. "Until we understand that, we're not in a position to appraise the risk."

REMEDY: Konradi suggests IRBs tell investigators to paint a picture and use language that will help IRB members understand the procedures and risk from the perspective of a participant. They should describe the activities fully, say how long each one will take, and use descriptive language to show how the participant will experience the study's procedures. ■

State biobank collects bloodspots from newborn screening

Program seeks consent from new parents for research use of leftover samples

The state of Michigan has moved forward with its plan to store blood samples left over from screening newborns for medical conditions in a biorepository that will make the deidentified samples available for research.

Hospitals began last fall distributing information brochures and consent cards for the newly created Michigan BioTrust for Health to give to new parents.

In creating the program, Michigan officials are attempting to skirt controversies that have plagued other states, where parents rebelled against so-called "opt-out" procedures that allowed newborn bloodspots to be used for research unless parents contact the state to withdraw their child's samples.

By contrast, the Michigan Department of Community Health (MDCH) requires explicit permission from all parents of newborns to use the infants' bloodspots in the BioTrust. To do so, they launched an ambitious education program to train nurses in hospitals across the state to explain the BioTrust to new parents.

Carrie Langbo, MS, CGC, BioTrust outreach coordinator for the MDCH in Lansing, says the

state sought public input about the BioTrust plan using phone and online surveys, contacting health advocacy groups and holding focus groups across the state.

Most Michigan residents surveyed — anywhere from 79 percent to 99 percent — strongly favored using leftover bloodspots for research. But Langbo says a "significant minority" also believed parents should be asked to give permission for their children's bloodspots to be used.

MDCH's then-IRB Chairman **Harry McGee**, PhD agreed.

"It's a basic respect for persons that you ask somebody for their permission if you want to use those stored bloodspots for research, even if you're not providing any identifying information," says McGee, who is currently chairman of the social/behavioral IRB at Michigan State University in East Lansing. "My feeling was, regardless of the regulations, it was the right thing to do."

Previously, he says, bloodspots had been stored for specific purposes — quality assurance of the screening procedures and to allow parents and adults to access their own bloodspots if needed later.

McGee says that when his IRB consulted the federal Office for Human Research Protections, OHRP agreed that the purpose of storing the bloodspots had changed and that using them for research would require either consent from parents of a waiver of consent.

"And we didn't feel like we could meet the criteria for waiving consent," McGee says.

Training nurses

With its IRB mandating an "opt-in" approach, the MDCH created a training program for nurses in Michigan's 80-plus birthing hospitals so that they could describe the BioTrust to parents and seek permission to include their children's leftover bloodspots.

Throughout the process, Langbo says, it was important to ensure that parents understood the difference between the newborn screening, which is state-mandated, and the BioTrust, which is not.

"We needed staff to explain to parents that what you're consenting for is the use of the leftover dried bloodspots through the BioTrust and not the newborn screening itself," Langbo says.

Although the screening is technically mandatory, she says parents can decline it. Langbo and McGee say Michigan officials didn't want confusion over the BioTrust to cause parents to refuse the screenings, which can identify rare but serious disorders that require early medical treatment.

"I thought that if that was going to jeopardize newborn screening, that we shouldn't allow it at all," McGee says. "The challenge was to have an educational process that allowed the newborn screening program to continue to function as it had, but then to give people the choice to say whether this blood that was already going to be stored for newborn screening could be used for research."

The department piloted the education and consent process at 11 hospitals across the state in spring 2010. Training sessions were held for nursing staff and brochures and consent forms, located on the back of newborn screening cards, were distributed.

"But we were really very relieved that we saw great reception from all the staff," Langbo says. "They felt that it bolstered awareness about newborn screening with their patients and within the staff themselves."

One problem did turn up during the pilot program. Initially, the consent on the newborn screening card only had space for a parent to agree to research use of the bloodspots. Parents who declined were instructed not to sign the card, and it would be returned to the MDCH.

This made some parents uncomfortable, Langbo says. Worried that someone would fill in the card afterward, they would write the word "declined" on the signature line. But Langbo says this approach created problems for staff reading the cards who sometimes couldn't determine whether the parent was signing or declining.

For the later rollout of the program to the entire state, the MDCH changed the card to provide a box at the top that the nurse could check if the information was presented to the parents but the parents declined to allow the use of the bloodspots in the BioTrust.

In expanding the program to all of Michigan's birthing hospitals in fall 2010, the state began offering several means of training nurses. In addition to live inservices, the department conducted a webcast that hospitals could access, and then posted the presentation on its website in a PowerPoint format for hospitals to see later. All the training programs allow nurses to earn continuing education credits.

"It was great to see that hospitals are actually combining it as part of their new orientation for staff," Langbo says.

Community board partners with IRB

At every step along the way, both the MDCH IRB and a community values advisory board have approved the materials and educational components.

The community board was convened in 2009, with members drawn from various community organizations and from different populations in the state.

"They were charged with meeting quarterly, but actually have met monthly, up until a few months ago," Langbo says. "They went through all of the informed consent material, line by line, word by word, making sure that it would meet the needs of all the communities in the state, including all educational levels."

She says the interaction between the MDCH IRB and the community board has been key to the success of the project. One community values advisory board member now serves as a full member of the IRB.

In addition, McGee says he made it clear to the community board that the IRB may come to them for advice if situations arise that fall outside the IRB's regulatory authority, particularly as it reviews future research proposals that would seek to use the bloodspots.

"For example, the IRB regulations are intended to protect human subjects rather than groups, and any research that may involve potential risk to a group rather than an individual would be something that we'd come to the community values advisory board for advice on," he says.

Langbo believes that seeking community input, as well as making the process transparent, has helped Michigan avoid problems seen in other states, where parents have refused to allow their children to be screened or even sued the state to prevent research from being done with newborn bloodspots.

"In discussions with states where they don't have a consent process in place, we're hearing that they're getting a significant number of parents declining newborn screening because they're upset about not being involved in the process," she says.

"We're hoping this will work and will have an opposite effect," Langbo says. " . . . That parents will feel more in control of what happens to those specimens by having those conversations." ■

Researchers ignore past studies when conducting new ones

Failing to consider past studies can lead to unnecessary risks for subjects

A recent analysis of clinical trials showed that researchers routinely ignored previously published and relevant clinical trials when conducting their own studies.

On average, researchers whose papers were analyzed cited less than 21 percent of previously published relevant studies. In some cases, an investigator would present a paper as the first study of its kind when a search of the literature showed that it wasn't, says **Karen Robinson**, PhD, assistant professor of medicine at the Johns Hopkins University School of Medicine in Baltimore, MD.

Ignoring previous studies on the same topic can lead to wasting resources trying to answer a question that's already been answered, Robinson says.

And from the point of view of IRBs, it can lead subjects to be enrolled in unnecessary studies.

"At the beginning of a trial, a complete consideration of the existing evidence is needed to justify a trial," Robinson says. "So that patients who are signing up to join your trial know first of all that they're signing up to answer a question that needs to be answered."

Failing to review relevant studies also can lead to unnecessary risks for participants, such as their being assigned to the placebo arm of a study when the efficacy of the study drug already has been proven in prior research.

Systemic problem?

Robinson says previous studies have shown a lack of citations in clinical research. But her group's study was more expansive, looking at meta-analyses covering 19 specialties, including pediatrics, gynecology, oncology, psychiatry and surgery.

"We wanted to get a handle on whether this was a systemic problem," Robinson says. "Were these just anecdotal pieces of evidence from this prior literature, or is there something more widespread going on?"

The team looked at 227 meta-analyses published in 2004, comprising 1,523 separate clinical trials. Although the meta-analyses were published in 2004, the trials included in them dated back as far as 1963. For each separate study, the group determined the number of prior trials cited, as well as the number of relevant citations available to be listed.

Results showed that of 1,101 articles for which there had been at least five previous relevant papers, 46 percent cited no more than one of them. As time went on and the number of prior trials increased, the number of citations didn't increase along with it.

"Hence, the more (randomized controlled trial) evidence that existed, the more likely that investigators on subsequent trials would ignore it," Robinson and her colleagues wrote in an article published recently in the *Annals of Internal Medicine*.[1]

Robinson says there are many possible explanations for the omissions of previous research.

One sometimes offered by researchers is that journals' space limitations don't allow them to list all of the previous relevant studies, but Robinson says that is more of an excuse than a legitimate reason.

She says funding agencies and journals are more interested in novel information and unique trials, and so researchers may feel pressure to minimize previous similar research.

"Obviously, to be able to say, 'My trial is the first one or the first one of its kind,' is useful, so maybe referring to other trials with the same question won't help make their case," she says.

Changing research culture

Beyond that, Robinson says the research culture doesn't sufficiently emphasize extensive research before embarking on a new clinical trial.

"Investigators aren't taught to do this sort of thing, and there's not a culture of expectation that they do so," she says.

"We now recognize that a consideration of the best available evidence is the best way to inform health care decision-making, and I'd like to see that same mentality used for developing hypotheses, designing trials and interpreting trials," Robinson says. Those three things should be based on the best available evidence."

She says IRBs have an important role to play in encouraging the change in culture. She says they should require that researchers show they have done a systematic review of the literature for relevant studies.

"Maybe a researcher is the first (to explore a particular question), but IRBs should ask investigators how do you know you're the first?" Robinson says. "Did you search for other related trials? Did you do a comprehensive search?

"I think investigators should be required to do a systematic review and IRBs need to be in a position to evaluate whether they have actually done that."

She says some funding agencies and journals have instituted requirements in recent years that researchers conduct systematic reviews.

Robinson says she's continuing to look at this issue and is examining meta-analyses from 2009 to see if citations have improved.

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Questions about dating violence can help subjects, study says

Personal benefits and negative reactions reported by men, women, victims and perpetrators

IRBs sometimes balk at studies that ask sensitive questions about topics such as sex and violence, based on concerns that participants may find them distressing.

This concern persists, despite several studies over the years that have shown that negative reactions to such questions are often balanced by positive benefits, such as providing participants with useful insights into their lives.

One of the latest studies to explore this issue looked at dating violence among college students. Men and women were asked about their experiences either as victims or perpetrators of psychological, physical and sexual abuse in their dating relationships. In addition, they were asked about their reactions to the questions.

The results showed that while some participants did have mildly negative emotional reactions to the questions, both victims and perpetrators of dating violence did perceive some personal benefits from

their participation.

The questions about participants' reactions actually came at the suggestion of an IRB reviewing the proposed dating violence study, says **Ryan Shorey**, MA, a clinical psychology doctoral student at the University of Tennessee – Knoxville. Shorey was the lead author of an article about the study that appeared recently in the online edition of the *Journal of Interpersonal Violence*.[1]

"The IRB was having some concerns around emotional distress and wondered how we could go about assessing that," Shorey says. "It was their suggestion, which was great, since they wanted some scientific evidence around it."

Shorey says he hopes that IRBs will use evidence from studies such as this one to do more scientifically based cost-benefit analyses of studies that ask potentially sensitive questions.

"Although there were some mild negative reactions, overall, they weren't very high, and we really feel that the benefits did outweigh the risks," he says.

College students surveyed

Shorey's group used an existing measure, the Reactions to Research Participation Questionnaire, to gauge attitudes in the study. Participants are asked a number of questions about their reactions, including whether the survey raised unexpected emotional issues, whether they found the questions too personal, and whether they were glad that they had been asked to participate.

The survey, including the reaction questions, was administered to 260 college students who were recruited from introductory psychology classes. They filled out the written surveys in a classroom with a research assistant present to answer questions if necessary.

Results did show negative reactions from some participants. In general, male victims of psychological and physical abuse and male perpetrators of physical abuse had more negative reactions than non-victims and non-perpetrators, particularly in cases of high-frequency abuse. But nearly all of the same groups also reported more positive personal benefits to participation than those not involved in dating violence.

Similarly, female victims and perpetrators of abuse saw greater benefits to participating than non-victims and non-perpetrators.

Shorey says the benefits of participating in the study seemed to be greater for men than for women.

"When we think about it, we know women disclose this information more, to people such as friends and family," he says. "It might be the fact that (the study) was an opportunity for the men to get some of this out there and tell somebody about it in a way that wasn't one-on-one verbally communicated."

Including possible benefits in consent

Shorey says IRBs should allow informed consent documents in studies such as this one to include information about potential benefits to participants.

"We've had issues with some IRBs not believing this information, when we tell the students that they might gain some insights into themselves, their behaviors and their relationships," Shorey says. "But on the positive side of the study, that's what it showed — they get some positives out of it, even with these sensitive questions."

At the same time, Shorey says the risks of negative reactions to the questions also should be made clear in the informed consent, Shorey says.

"It's important that informed consent have at least a statement that some questions are going to be sensitive and fairly personal, and it may be upsetting to recall some of that information," he says. "You should let them know that they can discontinue if they want to or that there are resources they can contact if they need it when they are done participating."

In this study, Shorey says, students were given contact information for campus counseling services and a research staffer was available in the room if students needed someone to talk to immediately.[1]

Researchers may have to go further in situations where participants don't have easy access to help, Shorey says. For example, it might be preferable to have a PhD or a graduate research assistant monitoring the survey.

"In our research with, say, battered women, we have to have very different resources available to them afterward — shelters, community mental health centers," he says. "I think in those situations, where there isn't something readily available and free, it would be beneficial to have somebody there who is more trained than an undergraduate research assistant."

Shorey says it's important for IRBs to understand that a participant can be distressed by ques-

tions while still gaining positive benefits from answering them.

"This is the first study that looks at this with dating violence, but if you look at research with more traumatized populations such as battered women, you see that a lot," he says. "That it can be upsetting to talk about, but it's one of the first steps you go through in the healing process.

"Knowing that both can happen would certainly be beneficial," Shorey says. "Some of the concern with IRBs is that they don't potentially see the benefit, other than to science. They don't see that the research participant could benefit, too."

REFERENCE

1. Shorey RC, Cornelius TL, Bell KM. Reactions to participating in dating violence research: Are our questions distressing Participants? *J Interpers Violence* 2010 Dec 13 (Epub). ■

BINDERS AVAILABLE

IRB ADVISOR has sturdy plastic binders available if you would like to store back issues of the newsletters. To request a binder, please e-mail binders@ahcmedia. com. Please be sure to include the name of the newsletter, the subscriber number and your full address.

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CNE/CME OBJECTIVES/ INSTRUCTIONS

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

- Office formed to handle PI-initiated study oversight
- Improve protocol conformity with regulations
- Translators and interpreters can bridge cultural gaps
- Working with DSMBs to improve participants' safety

CNE/CME QUESTIONS

13. Which of the following is a good reason for an IRB office to collect and analyze operational metrics?
A. Data can help an IRB director of employee use time more efficiently and identify priorities.
B. Metrics can help when IRB offices are scheduling continuing reviews.
C. Data analysis can help with improving the IRB's turnaround time on protocol reviews.
D. All of the above

14. How might investigators improve protocol applications to avoid common mistakes that lead to a lengthier review process?
A. Send the IRB office the rough draft and request an editing review first.
B. Have a second person check the application for common mistakes, including grammatical errors, misspellings, and lack of precision.
C. Turn in the application 48 hours before the IRB's review meeting so there is too little time for the IRB office to send the application back, asking for more details.
D. None of the above

15. According to a survey of college students regarding dating violence, who appeared to benefit more from answering the questions?
a. Men
b. Women
c. Men and women appeared to benefit equally

16. Researchers whose clinical trials were analyzed in a recent study cited a little over half of previously published and relevant studies.
A. True
B. False

Answers: 13. D; 14. B; 15. A; 16. B