IRB ADVISOR

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INSIDE

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A Fresh Method to Adverse Event Tracking in Behavioral Studies

More adverse events are captured

By Melinda Young, Author

Adverse events related to pharmaceutical or device clinical trials are fairly straightforward. If the patient has a medical issue while volunteering for a study, then it should be monitored. But how might researchers in social-behavioral studies, involving psychotherapy, monitor symptoms believed to be part of the normal therapeutic process?

This is a question researchers wanted to answer with a study of a state-of-the-art adverse event monitoring program for behavioral health clinical trials. Funded by the U.S. Department of Defense and Veterans Affairs, the effort involved testing evidence-based behavioral therapies for post-traumatic stress disorder (PTSD) in active duty military personnel.[1]

"Many of us come to adverse event monitoring from the FDA perspective," says **Stacey Young-McCaughan**, RN, PhD, professor in the division of behavioral medicine in the department of psychiatry at University of Texas Health Science Center in San Antonio.

"I'M A NURSE AND I NEVER CONDUCTED DRUG TRIALS, BUT SITTING ON IRBS AND CHAIRING IRBS HAVE SHOWN MANY ADVERSE EVENTS."

"I'm a nurse and I never conducted drug trials, but sitting on IRBs and chairing IRBs have shown many adverse events," she says. "Here, we conduct clinical trials testing behavioral intervention for post-traumatic stress disorder and related conditions in military service men, women, and recently released veterans."

Through the South Texas Research Organization Network Guiding Studies on Trauma and Resilience (STRONG STAR), there have been more than two

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AUTHOR: Melinda Young
MEDICAL WRITER: Gary Evans
EDITOR: Jill Drachenberg
EDITOR: Dana Spector
AHC MEDIA EDITORIAL GROUP MANAGER: Terrey L. Hatcher
SENIOR ACCREDITATIONS OFFICER: Lee Landenberger

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(404) 262-5508.

dozen randomized, controlled trials testing various behavioral health interventions among the more than 1,000 study participants.[1]

Some of the adverse event (AE) classifications captured in the AE monitoring were sleep-insomnia, medical-surgery, flashback, irritability, suicide-ideation, pain-headache, and depression.[1]

Defining serious adverse events (SAEs) is especially challenging in behavioral science research.

"You're living your life and develop a hernia or need a knee replacement or have an auto accident," Young-McCaughan says. "If you have an overnight hospitalization that's considered a SAE; although it's not related to the study, it's considered a SAE and is reportable to the regulatory body."

Federal regulations require unrelated AEs to be collected. If the AEs are unrelated to study participation, they do not need expedited reporting to regulatory agencies, per Unanticipated Problems guidance.

"We just document them as unrelated to the study that's going on," says Young-McCaughan.

Regulations define adverse events as any unfavorable medical occurrence in human subjects, including abnormal lab or physical exam findings, symptoms, or disease that is associated with the subject's participation in research, whether or not it's related to the research participation.

"It's always good to keep track of them," Young-McCaughan says. "Remember Cox-2 inhibitors? Nobody was expecting increased incidences of myocardial infarction, and then they saw a number of those and said, 'Wait a minute, there are too many of these MIs here — let's go back and take a look.'"

The benefit of adverse event monitoring is that it can dispel some misconceptions. For instance, it was standard practice before to not enroll anyone who expressed any sort of suicidality, she says.

Researchers initially did not want to enroll potentially suicidal subjects for safety concerns, but they've discovered that enrolling them with a safety plan works to everyone's benefit, Young-McCaughan says.

For service members with PTSD, engaging in therapy and addressing their primary concerns also has the side effect of reducing potential suicidality.

"If they get their PTSD under control, they don't feel as hopeless and helpless," Young-McCaughan says. "It gives us and others a lot of confidence in using behavioral therapies for people who have suicidality."

By putting rigor and definition into an adverse monitoring program, it can help investigators develop a symptom profile so individuals can be fully informed about side effects, she says.

"We have published one article on adverse event reporting, and we didn't find any other articles of people thinking about this," she says.

For this study, researchers had study coordinators take careful notes of what research participants said during visits. They asked participants if anything had changed since they were last there, and explained that the coordinator wanted to make sure the person could safely participate in the study, Young-McCaughan suggests.

"We would ask the person who is writing down the information for their impression of the severity of the event and whether it was related or not to the study," she explains. "Then we take the event or series of events to the investigator and have a group discussion about what happened and whether it was an adverse event, a

serious adverse event, or related or expected."

Setting up an adverse event monitoring system for this type of research was a challenge, Young-McCaughan notes.

"We started out with checklists, asking, 'Do you have nausea, vomiting, headaches?' but it felt too constraining," she says. "So we took a broad-based approach, asking, 'Has anything changed since we last saw you?'"

They define change as any health status change since baseline.

Helping study participants understand what to expect also was challenging. "With behavioral health, what is the chance you'll feel worse before you'll feel better?" Young-McCaughan asks. "What is the chance of having worse sleep or worse nightmares? We didn't know what the answer was."

This data-driven approach is more useful than having investigators and IRBs use their intuition to determine risks.

"Instead of letting rumors abound about how traumatic these interventions can be, let's put data behind it so we'll know what to expect," Young-McCaughan says. "For people wanting to use these data in clinical practice, therapists who read the study might say, 'This looks like a good therapy and I want to use it. I can tell my patients they'll have some side effects, but this won't be an overwhelming, unmanageable type of therapy for them to handle.'"

For researchers who come from a laboratory setting, the process of identifying and monitoring adverse events has been a learning curve, says **Allison Hancock**, PhD, assistant professor of the division of behavioral medicine in the department of psychiatry at University of Texas Health Science Center.

"I have an experimental psychiatry background, and watching this process unfold in clinical trials with less structure and control around them has been eye-opening," Hancock says. "It's been helpful to the investigators, and coming from a regulatory perspective, the biggest help is it allows us to inform the participants more accurately."

For example, if investigators see that many participants have difficulty with insomnia or nightmares, they can update the informed consent to inform participants of this possible side effect, Hancock says. ■

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No ROMP in the Park: The Complex Intersection Between QI and Clinical Research

What triggers IRB review, who obtains consent, or can it be waived?

Somewhere between typical human research and clinical practice, there is gray area assigned the acronym ROMP — "research on medical practices" — that includes activities such as continuous quality improvement, comparative effectiveness research, and electronic medical record review, the authors of a new study explain.[1]

"The fact that ROMP shares some characteristics with clinical research and some with usual clinical practice leads to uncertainty as to how the regulations should be applied to ROMP," they report. "In particular, ROMP that uses a randomized approach, wherein patients are randomized to different treatments already utilized in usual clinical care so that outcomes can be compared, shares some characteristics with research to evaluate new treatments, such as an explicit goal of generating generalizable knowledge. But unlike in studies of new treatments, all participants in ROMP receive a commonly accepted treatment."

In 2014 draft guidance by the Office for Human Research Protections — which has not been finalized — OHRP explains that ROMP is "designed to evaluate treatments or procedures that are medically recognized standards of care. … Reasonably foreseeable risks must be described to prospective subjects when seeking their informed consent."[2] As the guidance has not been formally completed, IRBs and researchers may have different interpretations and opinions of ROMP activities. To assess this, researchers surveyed IRB members of Public Responsibility in Medicine and Research (PRIM&R).

"We found that PRIM&R members with experience as IRB

personnel expressed varying views when responding to three key issues: what triggers IRB review; who should obtain consent; and when consent should be waived," they reported.

The survey netted 537 responses from people who reported they had experience as IRB personnel. In terms of IRB review, 81.8% indicated that randomly assigning patients to use specific treatments should always trigger a full review. "Few respondents indicated that IRB review should always take place when standard clinical pathways are used to determine patients' treatments," the researchers found.

When respondents were asked who should obtain consent for ROMP initiatives, 49.2% agreed that it could be done by the patient's clinician, or an investigator, research nurse, or study coordinator not involved with the patient's care. Nearly one-third of respondents indicated that all but a patient's clinician may ethically obtain consent, but 9.5% said that only the patient's clinician should seek informed consent.

As an example of the different views expressed, the researchers noted that one commented that it would be "nearly impossible for a patient not to experience undue influence" when recruited by their direct caregiver. In contrast, another argued that the treating physician could best assess the patient's concerns about receiving randomized care.

Nearly two-thirds of respondents agreed that informed consent could be waived if patients were randomized but still received "usual care." However, 36.6% said informed consent should not be waived for patients who who were going to receive randomized care as part of a ROMP project.

Thus, there are several areas of discord that must be resolved to protect "research participants while simultaneously allowing important quality improvement initiatives to continue," the researchers concluded.

IRB Q&A

Lead author **Kathryn M. Porter**, JD, MPH, of the Seattle Children's Research Institute, agreed to field a few questions on this complex topic.

IRB Advisor: This is certainly a thorny area, as ROMP quality improvement activities may mimic and even potentially morph into more traditional human research. First, what are the pros and cons of the current situation, which appears to be that IRBs have considerable variation on their approaches to this problem? Is there substantial benefit to be gained in terms of quality improvement and human protections to develop a standardized approach for all IRBs?

> "WHILE CONSIDERING COMMUNITY INTERESTS AND VALUES IS WORTHWHILE, IT'S IMPORTANT TO WORK TOWARD SOME LEVEL OF CONSISTENCY ACROSS IRBS AS WELL."

Porter: One of the concerns with IRB variability is that it suggests both over- and under-regulation. Over-regulation can stifle scientific and medical progress while under-regulation runs the risk of endangering research participants. Variability also creates complexity for multicenter trials that strive for cross-site consistency, but may end up faced with multiple rules and guidelines from individual IRBs. While considering community interests and values is worthwhile, it's important to work toward some level of consistency across IRBs as well.

IRB Advisor: The example of informed consent seems particularly tricky, since it appears valid arguments can be made that the treating clinician is the most likely to know the patient risk, but also could have undue influence in the consent decision. How will your research attempt to reconcile this conundrum, or might this be left to the local IRB?

Porter: Unfortunately, our research doesn't answer this question — yet. The undue influence argument is used a lot, and for good reason. At the same time, our previous research suggests that participants highly value the relationship they have with their doctor and often want their doctor to be the one who talks to them about research opportunities.

We've also seen evidence that some participants would rely on their doctor's opinion when deciding whether to participate in a particular research study, suggesting that sometimes doctor influence isn't "undue." So this is definitely an area that is ripe for future research. We want to better understand how and when people make the decision about whether to participate in research, as well as how much

influence — undue or otherwise — doctors actually have in that process.

IRB Advisor: What would be the downside of erring on the side of human protections and treating ROMP as de facto human research with its attendant protections, even in comparing drugs already known to be safe and effective among randomized patient groups?

Porter: It's important to distinguish between activities like quality improvement and activities like ROMP. ROMP should be treated as research, because that's what it is. But our current regulatory system is designed to give IRBs some flexibility, depending on the level of risk of a particular research study. Because the drugs being compared in ROMP studies have all been determined to be safe and effective, ROMP is a relatively low-risk kind of research. And with low-risk research, IRBs have the ability to streamline the informed consent process in a way that facilitates research and improves participant understanding. Treating ROMP the same as higher-risk research has its downsides — it would require an approach to informed consent that may be more complicated to administer, less likely to be read or understood by participants, and an unnecessary use of limited resources. ■

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Ethical Issues of Research Recruiting on Social Media

IRBs will be dealing more with this expanding issue

Not surprisingly, the exploding social media landscape is fraught with ethical intrigue for researchers who seek to recruit human research subjects for clinical trials.

There are obvious concerns about confidentiality, informed consent, and other ethical issues, but there is also an ever-expanding database that could lead recruiters to ideal subjects for a given clinical trial. With little in the way of regulations or formal guidance for this expanding area, researchers recently outlined a practical path through this potential minefield and included a checklist for IRBs. *(See summary points, page 43.)*

"While the ethically relevant differences between social media and more customary recruitment techniques should not be exaggerated, these materials can help to serve as a roadmap for its potentially unfamiliar aspects and contribute to putting social media recruitment in proper ethical perspective as a valuable recruitment tool," the authors conclude.

For further insight, *IRB Advisor* interviewed the lead author of the paper, **Luke Gelinas**, PhD, MA, a Harvard Catalyst fellow in clinical research ethics at the Petrie-Flom Center of Harvard Law School.

IRB Advisor: With regard to social media and research recruitment, is this a case where technology has essentially outstripped ethical oversight?

Gelinas: Yes, that's my sense. You have a couple of different things. One is that you have people in industry-sponsored trials that are rushing full bore to capitalize on the opportunities that social media provides in terms of research participants. The problem is there is really no discussion of the ethics and really no regulatory or ethical guidance available to sort this out.

This motivated our project — we were sympathetic to want to promote the use of social media to recruit participants. We just think it should be done in ways that are ethical. So we really set out to provide some guidance that would allow IRBs to be more comfortable reviewing this, that would aid them in their review of social media recruiting techniques, and ultimately to help them use this [platform] both more and also better.

IRB Advisor: What are the implications of the current situation for IRBs?

Gelinas: We in the IRB community — and I sit on an IRB — have a duty to be thinking about these things more than we currently are. We are kind of lagging behind the social media space, so one thing we are trying to do with this project

is get this on people's radar in the IRB world, and give them the tools they need to adequately review social media recruitment. Because it's not going away — social media is everywhere and we are going to see more and more research activities involving it. We in the IRB world need to start grappling with this and doing our best to catch up.

IRB Advisor: There is almost the assumption that anything on social media is not private, but when it comes to research, that is not necessarily the case. As you note in the article, "typically this information has not been shared by social media users for the advancement of generalizable knowledge and health purposes."

Gelinas: One of the main ethical concerns is that you have people posting all kinds of stuff on social media — sometimes even stuff that perhaps they shouldn't have. People post things that might pose risk to them, that might stigmatize them or lead to forms of discrimination. People don't tend to worry about this too much in terms of general social media use. You see it all the time. So it's sort of challenging when researchers get involved.

Researchers are used to being conscientious about privacy norms. They want to respect privacy and respect confidentiality, but then you have this space where people don't seem to care at all about it. So the question is, how should researchers deal this space?

We think that researchers should at least take some caution and not magnify the privacy risk. A lot of people don't understand the privacy risk and may struggle with how to set their privacy setting on Facebook and these other platforms. They don't comprehend it, so researchers have some obligation to realize, if this person posted something really sensitive — which was probably a bad idea — the least I can do is not publicize it further and not magnify the chances of harm.

For example, a researcher encounters a tweet that says something like, "I am really struggling with my depression. My meds aren't working and I'm looking for a clinical trial." It may be OK for the researcher to reach out to this person and offer them participation in a clinical trial, but the way in which they do that could be really important. They shouldn't send them a public tweet back that would further publicize the [original] tweet that was perhaps ill-advised. In a social media platform, every time you retweet or respond to something it could be coming up on everyone's screens. So it may be all right to reach out to this person, but send them a private message on the side. That's just one example of the kind of thing we think researchers should be doing in the social media space.

IRB Advisor: Recruitment of subjects is a common problem, but there may be people or groups on social media that, as you say, have some medical condition and want to get in a clinical trial. How can you ethically use social media for research recruitment?

Gelinas: It is a huge challenge, and the basic challenge is really an ethical one. Say you have low recruitment rates and the study may not enroll enough people to be adequately powered to generate generalizable knowledge. The value of that knowledge may be what justifies exposing the subjects to risk. The researcher may think it is OK to expose these subjects to risk because we are going to get this really useful knowledge. On the other hand, if we don't get that knowledge because the studies are not recruiting enough people, then it looks like the risk to the subjects was unjustified. It's a big problem.

IRB Advisor: In the paper, you cite the need to provide both respect for the privacy of social media users and investigator transparency.

Gelinas: In terms of actually recruiting on social media, there are kind of two ways to go about it. One way is analogous to the traditional way of using posters or flyers at bus stops or subways. You could just post advertising in online spaces giving the contact name of the researcher for more information about the study. Let social media users contact you on their own.

The other way to do this is to be more active, sort of immersing yourself in online communities as a researcher looking for people who might be a good fit for your study based on their participation in certain groups or their online activities. There may be a group for cancer survivors or cancer patients and there is really no restriction on who is participating. As a researcher, you might think if I start participating in this conversation maybe I will come across people who are good fits for my study. Both of these types of recruitment may be OK, but the more targeted type is a little bit more ethically tricky because it raises questions about whether people really want researchers "lurking" around these sites and observing people's online behavior. That raises some ethical questions and it requires more ethical sensitivity. ■

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Social Media Research Recruitment Checklist

Take-home tips for a rapidly emerging area

The following are key points summarized from a recently published checklist for IRB evaluation of social medial recruitment proposals from investigators. See the referenced article for the full context and complete list.[1]

- Seek to normalize social media recruitment to the extent possible, drawing analogies to traditional recruitment efforts.
- Ensure that the proposed online recruitment strategy complies with all applicable federal and state laws.
- Check that the investigator has certified compliance (or lack of noncompliance) between recruitment techniques and policies/terms of use of relevant websites.
- Ensure that proposed social media recruitment strategies respect all relevant ethical norms, including accurately describing the trial and assurances that recruitment will not involve methods that could embarrass or stigmatize potential participants.
- Ensure that investigators will obtain consent from current participants before they approach members of their online network for recruitment via their network or invite individuals to approach members of their network on research team's behalf.
- Ensure that a communication plan is in place for how the research team will handle online communication from enrolled participants that threatens the integrity of study. ■

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IRB Gets New Researchers' Attention With Visually Clever Infographics

Illustrations work on cellphones

As the IRB at Montclair State University in Montclair, NJ, worked on creating a culture of compliance, IRB leaders learned that new researchers, including students, pay more attention to policies and regulations when they're spelled out in more pictures than words.

"About 40% of our submissions are from students, and we completely understand that a lot of what we're asking for in terms of compliance has to be relayed in a way that is simple," says **Hila Berger**, research compliance officer at Montclair State University.

Creating infographics to illustrate educational materials, workshops, and marketing items was just one of the strategies the IRB employed to improve its compliance culture. *(For more informaton, see story on compliance strategies, page 44.)*

"We use infographics to simply relay complex information," she says. "So if a new policy or procedure comes up, or if we need a way to teach new faculty, we use infographics."

Berger has noticed more infographics being published in mainstream media. Also, students increasingly communicate with visual information. Even the federal Office of Research Integrity (ORI) has begun to use infographics to communicate some policies.

As Berger lives in a policy-driven environment, she began to think about how researchers would find long emails about new policies unappealing. She found a graphics program online that offers an education discount.

"They provide a template, and you put in your details," she explains. "If

you have only half an hour, you can easily create an infographic from their templates."

The IRB office has one employee proficient in creating graphics to take over the role for the past couple of years, Berger adds. *(Web extra: See sample infographic in* IRB Advisor *online at ahcmedia.com.)*

The infographics also are useful in training, as it helps connect the audience with the information. It helped the IRB spice up its email communications, with a side benefit of giving university professors a more effective way to teach their students about the IRB.

"Faculty members say they use the infographics I sent them to present to their students about the IRB process," Berger says. "They really like the infographics and respond well to them."

Even when educational material doesn't lend itself to eye-catching graphics, the IRB can turn the information into graphic bullet points with headlines in a different color. For example, the IRB created a one-page informational sheet about approaching and recruiting prospective participants. Its text is broken up by titles and bullet points. Here's what it says:

• **Advertisements:** Advertisements include posted and distributed flyers, letters, announcements placed online or sent by email, and information sheets sent to targeted groups of prospective participants. The IRB will review the advertisement and how it will be used to determine that it is not coercive and does not promise unreasonable benefits. The IRB reviews the final copy of the advertisements for readability.

"FACULTY MEMBERS SAY THEY USE THE INFOGRAPHICS I SENT THEM TO PRESENT TO THEIR STUDENTS ABOUT THE IRB PROCESS. THEY REALLY LIKE THE INFOGRAPHICS AND RESPOND WELL TO THEM."

• **IRB Tips:** Advertisements should provide the information that prospective participants need to determine their eligibility and interest. Include the following information, worded appropriately, in advertisements:

- "Montclair State University" header with the college and department name contact information;
- the purpose of the research;
- in summary form, the key inclusion/exclusion criteria that will be used to determine eligibility for the study;
- a brief list of key participation benefits/compensation, if any (e.g., a no-cost health examination, free parking, SONA credits);
- the time or other commitments required of the subjects;
- the person or office to contact for further information.

"We also try to use [graphics] for general newsletter layout," Berger says. "We have many compliance newsletters that communicate new procedures or new processes."

The challenge for IRBs is to create infographics that include all necessary information, but not too much.

"You can't fit everything into an infographic, so you have to highlight the most critical issues," Berger says. "People want tidbits of information."

Some of the easiest ways to use infographics is for marketing IRB events, such as workshops and training sessions.

"We send a visual set of information that guides people to when our workshops are offered, and it changes all the time," Berger says.

Since many people see information mainly through their cellphones, infographics are a way to grab their attention quickly, she adds. ■

Here Is a Nutshell Look at Ways to Improve Compliance

The Montclair State University IRB in Montclair, NJ, has a variety of strategies to improve research protection compliance, including providing educational materials with eye-catching infographics.

The following are some of the university's other methods:

• **Give away swag.** The IRB creates in-house magnets that researchers and professors can stick to their filing cabinets. The magnets say, "I Support Research at Montclair University," or "Keep Calm and

Ethical," says **Hila Berger**, research compliance officer at Montclair State University.

"These have been well-received, and they're on filing cabinets all over campus," she says.

• **Attend student research events.** The IRB sets up a table with a poster congratulating students and their faculty members at student research events for obtaining IRB approval.[1]

"My model is approachability, and I'm lucky enough to have a team that embraces that," Berger says.

• **Meet new faculty at their orientation.** IRB staff, wearing smiles, meet and greet new faculty on their own turf. This is a time when instructors are most open to hearing about how to conduct research properly, and often they will contact the IRB right after the event.[1]

• **Offer workshops and guest lectures.** Workshop surveys showed that after the instructional event, 92% of participants felt better prepared to submit to the IRB. IRB members provide classroom lectures as well, and these have proven to help both students and professors, who are reminded of existing and new policies.[1]

• **Make online learning modules available.** These modules can be integrated into an instructor's course. Almost all of the disciplines offer a research methods course, and these modules include recorded lectures, materials, and a quiz.[1]

• **Meet in person with researchers.** In recent years, these face-to-face meetings have increased, Berger notes.

"The IRB coordinator does the majority of those when there's a poorly-submitted application," she says. "She very nicely suggests they come in and discuss the IRB process and protocol, or sometimes the faculty member will say, 'Could you sit down with students to go over the protocol?'"

There were 48 face-to-face meetings in 2016, and these last anywhere from 30 minutes to an hour, Berger says. ■

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A Consent Consult Helps New Researchers With Informed Consent

Role-playing, teach-back help

IRBs can teach researchers how to create informed consent forms, but perhaps what they most need are lessons in how to handle the consent process.

"In the past we've done training sessions on informed consent," says **Michele Antisdel**, MBA, CIP, senior IRB regulatory analyst at Yale University Human Investigation Committee in New Haven, CT.

The sessions included common problems coordinators might have, how to notify subjects of significant new findings, and how to write informed consent forms.

"Those were very well received," Antisdel says. "But what we were hearing from the research community is they wanted more training on how to actually consent subjects, and that's where we came up with this training program."

The consent consult program started out as a group of 15 people who had responded to an email about the new training session on consent. "We asked them to bring us one of their consent forms, and we'd work on it," Antisdel says.

"It didn't work very well because the so-called subjects were other study coordinators, so giving feedback didn't work," she explains.

So the IRB changed the training sessions to feature smaller groups of less than five people. Each person would provide one informed consent form in advance. This way, the consent consultants could become familiar with the forms and highlight the most important elements — all before the meeting took place, she says.

The training begins with the Belmont Report, including the principle of respect for persons, and discusses autonomy, comprehension, voluntary participation, and the informed consent process.

Then IRB trainers go over each person's informed consent form, showing them the highlighted sections and the most important details, Antisdel says.

"We help them develop a checklist of things they can go over with

the subject," she adds. "We have a standard checklist with the required elements of consent."

They also teach study coordinators the teach-back method. "Don't make subjects feel like they're being taught in school and are being tested," Antisdel says. "Say to subjects, 'Just to make sure I'm doing a good job explaining it to you, would you tell me what I'm talking about?'"

This method makes people more comfortable, she notes.

These small-group training sessions also include role-playing. "That's when the fun starts," Antisdel says.

"The trainers know the consent forms and for most studies we're familiar with them anyway, so we would be the subject and start the role-playing," she explains. "In taking on the role of the subject, we would ask interesting questions."

For example, Antisdel once partnered in role-playing with a younger colleague, and they played parent and adolescent receiving consent for the teenager's study participation.

"We did bantering back and forth," she recalls. "As the mother of two daughters, it was easy for me to step into the role."

They portrayed the kind of scenario a coordinator might encounter, including dialogue about what would happen if the daughter became pregnant while enrolled in the study. The "mother," as portrayed by Antisdel, wanted to be told if her "daughter" became pregnant. But in their state, the law says the daughter is old enough to keep that information confidential.

"I was giving the investigator a hard time about it, but those are the kinds of things they have to think about when they're consenting subjects," Antisdel says.

> "I WAS GIVING THE INVESTIGATOR A HARD TIME ABOUT IT, BUT THOSE ARE THE KINDS OF THINGS THEY HAVE TO THINK ABOUT WHEN THEY'RE CONSENTING SUBJECTS."

IRB trainers also used the role-playing sessions to ask questions that reminded study coordinators of things they needed to mention during the consent process. For instance, maybe the study coordinator forgot during the role playing to tell the subject where to go for the study visit. The play-acting subject would then ask that question.

"Other things we do is act like we understood what's going on when it was clear we did not," Antisdel says. "We wanted to see if the study coordinator would realize we didn't understand."

They were able to trick the coordinators because one of the trainers has a different first language and would just nod her head when the coordinators were talking. "After a while, anyone could see that she wasn't getting it," Antisdel says.

The pretend subjects also asked whether they'd receive compensation for being in the study, asking this in such a way as to suggest that the compensation was more important to them than the study participation.

"The coordinators did pick up on that," she says.

The consent consults were well-received by the research community. They resulted in some unanticipated positive outcomes. One was that study coordinators would return to investigators, saying the consent language was too complicated and they needed to make consent more clear for subjects. Going through the training session with the role-playing piece taught coordinators how important it was to understand the study — for both coordinators and study participants, Antisdel says.

"They don't usually come back to us for another consult once they learn this," she notes. "We have seen amendment requests come through to make the consent easier to read, and we've probably done this process with close to 100 people over a year." ■

Student Receives IRB Approval to Collect and Display Comments from Sexual Assault Victims

"He was a friend of mine," the handwriting reads.

It is sewn on a sheet among a mix of similar, stark statements, written in different styles of handwriting to symbolize the individual source of each quote.

"I wish trying to erase my pain hadn't caused me more pain."

Anonymous by design, they nevertheless speak as both the one and the many, all students, all victims of campus sexual assault attending Notre Dame University or nearby St. Mary's College, both in South Bend, IN.

Student **Mary Kate Healey** came up with the idea as her thesis project for a BA in art design. To get clearance to collect and display the comments on a 4' x 9' sheet of fabric, Healey found she would need to go before the IRB at Notre Dame.

"I was a little bit concerned," she says. "It was something I was totally unfamiliar with. But luckily I have some friends who are psychology majors [with IRB experience] who really helped me through the process. The biggest thing the IRB wanted was to make sure everything was as ethical as possible."

For example, the 64 respondents were recruited for the project on Facebook, filling out an anonymous online survey that Healey created.

"What the IRB really wanted to know was that I had a good informed consent process," she says. "You couldn't participate unless you were at least 18 and clicked that you consented as part of the survey. The IRB also emphasized at the end of the survey I needed to supply resources for people who were [victims of sexual assault]. Not only resources on campus, but also national organizations."

To ensure confidentiality, the consent form did not ask for identifying information, and any names that were submitted with the comments were changed to pronouns. Thus, by design the study was an exercise in trust, as there was no way to establish if the comments were accurate.

"There was no way to verify if they were true, but I think that is part of the process," Healey says. "A lot of times [assault victims] are told they are lying: 'How do we know what you are saying is true?' So I think having this blind trust in people was important."

The IRB took a serious and thorough view of the project.

"I had to go through [the IRB] process a couple of times, mostly because I was unfamiliar with it," she says. "I didn't necessarily fill out everything to their standards the first couple of times. It was a process of several months. At least at Notre Dame, they want to make sure everything is perfect before you can be approved. There was some separate paperwork you have to fill out if you are advertising [recruiting] on social media."

For example, the IRB wanted to see the research recruitment language that would be posted on social media. After the hurdles were clear, the responses came in.

"Some people wrote very little," she says. "I had some people who wrote pages and pages. So I pulled out one or two sentences that I thought were really powerful."

She had different people write — thus using various styles of handwriting — the comments in dressmaker's invisible ink, which can serve as a stitching guide but then disappears.

"The other thing that was important to me was that there was no clear narrative," Healey says. "Some people had multiple quotes, some people just one, but you don't know who these people are or how they connect to each other. Once it was pretty full, I started stitching over it. I did the vast majority of it myself, but I also had sewing circles where I would invite people to volunteer and we would go to a very public part of campus and sew together. People would often come up to us and ask what we are doing because people don't usually sew at the library. It was another way to initiate dialogue."

The sewing and stitching as a form of communication and protest has roots in the suffragettes and the women's movement. The stitching of the words was labor intensive, but the greater toll was emotional in reading the testimony of the victims, she says. Along with the work of other Fine Arts students, the sheet is to be displayed April 7 at the Snite Museum of Art on the Notre Dame campus. ■

CME/CE OBJECTIVES

The CME/CE objectives for IRB Advisor are to help physicians and nurses be able to:

1. establish clinical trial programs using accepted ethical principles for human subject protection;
2. apply the mandated regulatory safeguards for patient recruitment, follow-up and reporting of findings for human subject research;
3. comply with the necessary educational requirements regarding informed consent and human subject research.

COMING IN FUTURE MONTHS

- Mentoring program helps investigators with real-time issues
- Is it QI or research? Question still needs answering
- How to divide up local IRB review and IRB of record review
- Which IRB regulations could be shelved in 2017?

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CME/CE INSTRUCTIONS

To earn credit for this activity, please follow these instructions:
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CME/CE QUESTIONS

1. **In behavioral health research, which of the following is not a possible adverse event?**

   a. Sleep-insomnia
   b. Flashback
   c. Pain-headache
   d. All of the above are possible adverse events.

2. **When using the teach-back method during an informed consent process with a study participant, which of the following is a good question to ask?**

   a. "What do you remember about the study's schedule?"
   b. "Just to make sure I'm doing a good job explaining it to you, would you tell me what I'm talking about?"
   c. "Why are you participating in this study?"
   d. All of the above

3. **In terms of recruiting research subjects on social media, investigators discouraged using online versions of posters or flyers, which have come to be associated with some highly publicized ethical lapses.**

   a. True
   b. False

4. **A survey of IRB members about research on medical practices (ROMP) delved into which primary concern?**

   a. What triggers IRB review
   b. Who should obtain consent
   c. When consent should be waived
   d. All of the above