IRB ADVISOR

Your Practical Guide To Institutional Review Board Management

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IN THIS ISSUE

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Use experts wisely to improve IRB review time, efficiency, and quality

"Content experts" serve as IRB-PI liaison

Major research institutions can improve their IRBs' efficiency and protocol review quality by making the best use of a resource they have in abundance: expert professors and scientists.

Calling such staff "content experts," an IRB chair at Nova Southeastern University in Fort Lauderdale, FL, finds that professors are in a much better position to look at protocols' content and to understand studies from researchers' perspective.

"Nova has a system where the entry point for protocols for IRB review is an individual who is generally a faculty member within the academic unit," says **Jaime A. Arango**, EdD, assistant director for education for human subjects protection at the University of Miami (FL). Arango also is with the CITI program at the University of Miami. Arango was an author of a study on using professors as content experts.[1]

The goal is for faculty members who are content experts in the same field as a particular study to work with investigators and help them identify systemic or design issues that could be resolved prior to the formal IRB protocol review, Arango explains.

Content experts help educate investigators and student researchers about the IRB review process, answering their questions much earlier than would occur without the experts' help, he adds.

"They have a similar background to the researchers and understand the methodology people in that profession typically use," says **Ana Imia Fins**, PhD, associate professor at the Center for Psychological Studies and IRB chair at Nova Southeastern University.

"We have at Nova 16 academic units or centers, as we call them," Fins explains. "Each of these centers has either a dean or director, and that person selects from faculty someone we refer to as a center representative for the IRB."

Each center representative serves as a liaison between the IRB office and the center, facilitating submissions from faculty and staff, and serving as a voting IRB member, she adds.

Most centers have one center representative and one alternative person, she says.

When protocols are submitted to the IRB office for expedited or full review, the center representative is the first contact from the IRB office that the principal investigator will contact, Fins says.

"The PI submits the protocol the center representative, who reviews it and gives feedback to the PI, asking for clarification, revision, and so on," Fins says. "It's an informal process and can be done verbally."

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Each center representative can provide this feedback in a way that works best for him or her. This might entail a center representative meeting with a principal investigator before the protocol is given to them to have questions answered.

"I've been a center representative, and many times I'd have a student with questions about the IRB protocol who would ask to meet with me," Fins says. "I'd give them a heads up on what the IRB was looking for so they could make sure everything was addressed in the protocol."

This proactive educational process helps to improve the quality of submitted protocols and can result in greater IRB review efficiency and reduced turnaround time.

Center representatives also serve as a less intimidating liaison or point person for IRB offices, Fins notes.

"It's nice to have someone at your own center and who is identified as an IRB person who can answer your questions," she adds.

There is a significant benefit for researchers to have someone who speaks their own language and understands their own area of study bridging the gap between investigators and IRB staff, Arango notes.

"They helped improve protocol submissions," he adds. "I definitely think they were helping investigators polish their submissions to get them ready for the next stage of the IRB."

When center representatives are asked a question they cannot answer they can call the IRB director or chair for assistance. The point is that they will help to facilitate a conversation, using their own expertise in the researcher's field to improve communication, Fins explains.

Nova Southeastern University appoints center representatives to three year terms, and they attend monthly IRB meetings during their terms. Their presence at meetings can help improve education throughout departments as they learn about protocol submission trends and issues and then take this information back to faculty and students conducting research.

"Center representatives can go back to investigators and say, 'Focus more on these aspects of your protocol: make sure these are areas you describe well and can hopefully reduce revisions that occur,'" Fins says.

REFERENCE:

1. Arango J, Fins A, Hamill T. Professors as content experts: the first line of IRB review. Poster presented at the 2010 Advancing Ethical Research Conference, held Dec. 6-8, 2010 in San Diego, CA. ■

Cancer protocol IRB has streamlined reviews

It reduces duplication, improves efficiency

An IRB dedicated to handling cancer research has shown benefits in efficiency and expertise when such a specialty IRB model is employed.

Since beginning six years ago, the Case Cancer Institutional Review Board in Cleveland, OH, has reduced duplication, improved protocol turn-around time, and given oncology investigators and clinical trial staff an IRB office that understands and caters to their specific questions and concerns, says **Mariesa Malinowski**, BS, CIP, administrative director of the Case Cancer IRB at Case Western Reserve University, School of Medicine in Cleveland.

The Case Cancer IRB, formed by the University Hospitals Case Medical Center and the Cleveland Clinic, meets weekly with 13 members at each meeting. They deal with 15-20 submissions on each agenda. There are 30 members total, but they change rotation on attendance so no one member is overburdened, Malinowski says.

"We added a layer in our standard operating procedures that says we will have a representative from each institution in attendance," she adds. "We share best practices with each hospital and have a true collaboration."

The IRB reviews protocols from more than 20 hospitals and reviews about 250 new applications a year. Many of these are long-term projects, so the overall caseload is about 1,000 active projects.

"We work closely with the cancer regulatory office department, and we can customize our schedule based on a study's needs," she says.

For instance, federally-funded cancer therapy evaluation programs need to have IRB reviews complete and approvals received within 90 days, so the Case Cancer IRB works with principal investigators (PIs) to make sure those are done in a timely manner, Malinowski adds.

The dedicated IRB is much more efficient at its work and has built procedures and policies that other IRBs might not have the time to handle.

"At the end of the day there's probably an overall cost savings," Malinowski says.

"We build procedures and policies that other IRBs wouldn't entertain," she says.

For instance, Case Cancer IRB addresses handling these areas:

— Multiple amendments
— Time and delays in paperwork
— Developing programs and procedures
— Rehiring and training
— Medical leave and cross-coverage of staff.

An example of the IRB's tools includes its research staff log developed last year. It defines the roles of various research staff and provides a table for listing their names, degrees, sites where research duties will be performed, whether they will obtain informed consent, and expiration date of human protection testing requirements.

The roles are defined in the staff log as follows:

• **Nurse coordinators:** Any direct research subject caregiver that with a nursing license that may have delegated responsibilities for completion of conducting informed consent processes, research related procedures, recording of adverse event(s), recording of data and/or documentation of case report forms.

• **Non-nurse coordinators:** Any direct research subject caregiver without a nursing license that may have delegated responsibilities for completion of conducting informed consent processes, research related procedures, recording of data, and/or documentation of case report forms.

• **Regulatory coordinators:** Staff responsible for the completion, submission and record keeping requirements of IRB related documents.

• **Data managers:** Staff responsible for the transcription and/or data entry of research related data.

The Case Cancer IRB gives each protocol high priority focus, Malinowski notes.

"My experience before was that you couldn't cater to just one study when you have 23 different departments," she explains. "You can only do your best, but now we have a smaller group and only work with one department."

The dedicated IRB has resulted in reduced complaints from researchers and their staff, and it's resulted in an IRB that is very responsive to any concerns or issues that arise, Malinowski says.

"We work as liaisons with their needs, customizing and catering to their needs," she explains. "When they're not happy they have our full attention, and we have multiple opportunities to meet and discuss issues."

Communication is the key to maintaining a successful relationship with research sites.

"You have to build in opportunities to meet

in person and discuss the needs of each of these institutions," Malinowski suggests. "Find the person or multiple people who are the key stakeholders in this and have regular meetings with them."

There often are cultural and operational differences between an IRB and research sites, so these face-to-face meetings are important for building trust and understanding.

This model for a specialized IRB could work for any large research institution that has a lot of research in one particular area, such as HIV disease, infectious diseases, transplant, heart surgery, etc.

"Look at your pool of protocols and see who are your dominating groups," Malinowski suggests. "It's worth your while to see who your collaborators are."

Launching a specialized IRB takes time because of the regulatory hurdles, including registering under one Federal Wide Assurance and entering institutional affiliation agreements.

"The agreements allow Case Western to be the IRB of record for all cancer-related research," Malinowski says. "It took eight months to complete the contract process."

The IRB decided to start with new protocols rather than to grandfather-in existing ones.

"In January, 2006, we established a committee, trained all members in all administrative details, setting a meeting place, and finding a way for the many physician members to commit to meetings every three to six weeks," she explains.

Having a large group of members who can alternate in attending meetings helps prevent member burnout.

One of the unanticipated benefits of forming the specialized IRB is that it has resulted in reduced duplication in various areas of human subjects research and review.

While the research institution knew it would create some efficiencies in cancer research reviews, there have been other efficiencies, as well.

For example, the old process in multisite studies was for each site to maintain its own paperwork and documentation. Now the sites can share this work, sharing the regulatory burden to reduce duplication and redundancy.

"They share a single review and now can share the need for emailing and communications and maintaining some files," Malinowski says.

"We started identifying duplication and saw more areas that could be reduced," she adds. "We are overall providing a cost savings." ■

IRB offices need to plan for when boss leaves

Key is having back-up personnel

All IRBs and IRB offices need to set up succession plans to ensure continuity in the event the IRB director or chair leave abruptly.

The goal is to keep the IRB program running during the short term in event of a chief person's retirement, illness, or other type of departure.

This is especially important for institutions at which one person handles the IRB office solely or with only a little administrative help, says **Kathy Ertell**, MS, CIH, program manager for the human research protection program at Pacific Northwest National Laboratory in Richland, WA.

"We are a small site with about 100 active protocols in our system, and we have a staff of one program manager, one part-time clerical assistant, and our IRB," Ertell explains.

The IRB office has a succession plan in place that includes procedures for how various tasks will be performed when Ertell is unavailable. The plan includes having a succession team, consisting of Ertell, the IRB chair, vice chair, and chair-in-training, stay in communication about projects so that one or more of the four could handle daily IRB activities when one person is unavailable.

"We've had several opportunities to exercise this program," Ertell says.

For instance, when Ertell was on six weeks medical leave in recent years, the office might have come to a standstill without implementation of its succession plan.

"Things went pretty well with the secretary screening all my emails and referring emails to the right person, and the administrative team kept things running while I was gone," Ertell says.

The IRB succession team filled in, handling paperwork, using email templates, and determining which new projects met the criteria for human subjects research, which usually are Ertell's tasks.

"They took the day-to-day phone calls asking whether something is human research and how to complete an IRB application," Ertell says. "We have a phone system that records phone voice mail on the computer, so the IRB assistant could listen to the messages and forward them to the right people."

Ertell offers these tips on how IRBs can plan for IRB administrator or chair succession:

- **Plan for various types of succession.**

There are various types of succession, including medical leave, death, job changes, and retirement. The IRB office should have succession plans for both long-term and short-term staffing issues, Ertell says.

Also, there should be a plan for what will happen if the IRB chair suddenly is not available.

"Transitions are very difficult for smaller organizations," she notes. "Larger organizations have lots of knowledgeable people in the work group, but smaller organizations in small metro areas have to think quite a ways ahead of they're going to replace a staff member."

With IRB chair succession, the key is to always have someone qualified who is waiting in the wings.

For example, the IRB chair's role could be taught to IRB vice-chairs, or IRBs could go with a co-chair model. Another option is to have a chair-in-training who could fill in at a moment's notice.

In large urban areas, an IRB office might be able to find qualified leaders who are available for transitional coverage, but this may not be an option for IRBs in more rural or smaller metro areas.

One way to prepare for IRB leadership transitions is to cross-train staff, Ertell suggests.

• Create an IRB office desk manual.

The desk manual provides detailed task information. The Pacific Northwest National Laboratory IRB office's desk manual is about 100 pages with an index and examples of documents used in research. It's kept right at the office assistant's fingertips, Ertell says.

"The desk manual tells someone that this is the day to send out continuing review notices to principal investigators," Ertell offers as an example.

"It lists the scheduled board meetings, who the members are and how to contact them, and which projects are due for full review and on which dates," she explains. "It sets up the mechanics for the meetings, listing what paperwork is distributed to members, how to distribute it — electronically or by mail, and which forms are needed and where they're located."

Other details the desk manual provides are as follows:

— What type of letterhead is used for approval letters?

— Where are the examples of continuing review letters?

— Which checklist is used to review projects?

— What should be done if someone calls to ask if their project qualifies as human subjects research?

— Who should speak with investigators?

The idea is for the desk manual to provide information about which IRB office tasks, including those that are critical and time-sensitive, and instructions on how to do these.

The desk manual might also include a list of valuable contacts in the areas of finance, legal, medical, research, and human resources, Ertell says.

• Look for qualified personnel in the region.

When it's time to replace someone, it helps to know the availability of qualified staff in a particular region.

For instance, IRBs in large urban areas might be able to find qualified IRB directors more easily than IRBs in a rural region, Ertell notes.

There might be people who have retired from IRB work or research work that would be willing to work on an interim basis. Someone who has experience might be moving to the area because of a spouse's work. So it is worthwhile searching for potential job candidates locally. But in some areas, IRBs need to expand their search.

"We are in the Eastern part of Washington state and have to think more creatively about hiring people," she says.

Finding someone with experience directing an IRB office or even working for an IRB office might not be an option. Instead, IRB directors could look for people who have the qualities and some of the research experience that is desired.

"We think about what kind of people would be good at this work," she adds. "I think ideally we'd want someone with some research background so they'd understand what the researchers are doing."

It also helps if the potential new hire has good interpersonal skills and has a background in interpreting organizational culture.

Another option is to ask sister organizations for help in filling a position. For instance, Pacific Northwest National Laboratory is part of the U.S. Department of Energy (DOE) national laboratory system. This means there are qualified IRB professionals across the country that might be retiring and willing to work at the Richland office while a permanent IRB director is recruited, Ertell says.

"Your human resources department could be in a position to assist you in finding someone on a temporary basis if need be," Ertell suggests. "They know the internal workings of the organization and how you staff, and they know how to find temporary staff."

At the very least, human resource departments can serve as a planning resource for getting the job descriptions accurate and assisting with continuity planning, Ertell says.

"Anytime you bring in a new staff member they're certainly going to be involved," she adds. "It

behooves any manager to know what the procedures are ahead of time and what will happen so you can be ready to act quickly." ■

Challenges of community engaged MH research

IRBs should avoid overprotection of community partners, experts say

Applying community engagement to mental health research can help researchers about design studies that incorporate the priorities of people with mental illness and arrive at the best strategies for working with them.

But IRBs can hinder this type of research by seeing the population as too vulnerable to fully participate and by requiring "paternalizing" protections not just for participants, but for peer evaluators who assist in the study, says a researcher who has specialized in community-engaged mental health research for more than 20 years.

"IRBs may overreach on protection of vulnerable populations that want to participate in research," says **Jean Campbell**, PhD, a research associate professor with the Missouri Institute of Mental Health in St. Louis. "They assume (peer evaluators) are part of the patient population, as opposed to the research population."

The push for community engagement in research in general has intensified in recent years, out of a sense of respect to the communities being studied, but also because it can help strengthen studies and aid in recruitment, says **James DuBois**, PhD, DSc, director of the Center for Research Ethics and Integrity at the Albert Gnaegi Center for Health Care Ethics at St. Louis University.

DuBois, who specializes in mental health research ethics, says that as he speaks with mental health consumers, he is struck by how their priorities about research differ from those of investigators.

For example, he says research tends to focus on efficacy of drugs, with less attention given to side effects that can be so disturbing to patients that they discontinue taking the medications.

In the area of mental health research ethics, DuBois says, the vast majority of NIH-funded studies focus on decision-making capacity.

"I think it's good research, I think it's an important topic," he says. "Studies clearly show that you can have a diagnosis of bipolar disorder or schizophrenia and frequently retain decision-making capacity. So in one sense, you could say it's de-stigmatizing.

"But I know some mental health consumers who say that the very fact that this is the topic they keep studying is stigmatizing, because it reinforces the idea that they don't have decisional capacity."

Treating evaluators as vulnerable

He says that while IRBs are most concerned with decisional capacity and undue influence, mental health consumers tend focus more on a study's benefits, whether payment for participation fairly compensates subjects and whether subjects face the possibility of being randomized to placebo or being asked to undergo a washout period.

Because of these differences, DuBois says it's important to include people with mental illness at the earliest stages of research projects.

But building in this type of involvement can raise challenges that don't come into play when dealing with other communities. Because of concerns about confidentiality, it may be as difficult to recruit mental health consumers to join an advisory board or to act as a peer evaluator as it is to recruit subjects.

Campbell says she sometimes must deal with gatekeepers just to put up posters in a community mental health center looking for workers. "I'd have to go through case managers who would try to evaluate whether people were well enough to do this work."

And IRBs may put extra restrictions on how they can participate on the research team.

"There is some assumption that the peer evaluators aren't going to maintain confidentiality as well, even if we show them the training that they're given," Campbell says. "IRBs worry that (participating) may endanger their mental health — the peer evaluators' mental health. These things aren't true, but they are the type of things that an IRB would question."

As one example, Campbell says, a research project that wants to post pictures of its staff, including peer evaluators, on a website might prompt concerns that the confidentiality of the peer evaluators is being breached, even if the evaluators give permission for the use of the photos.

"(The IRB is) concerned that you're violating their confidentiality as a patient, which doesn't make sense," she says.

Rigorous training 'positive'

Although tailoring human subjects protection training to lay people is a frequent concern in all types

of community research, Campbell says she doesn't view it as an insurmountable problem. She requires community research partners to take the online CITI course in protection of human subjects, even in some situations where an IRB doesn't require it.

"Yes, it is somewhat of a barrier, but I think it's good for people," she says. "I believe in the most rigorous training people can have. If you make the commitment to train people not just for your particular project, but for them to potentially develop leadership in their community or leadership as peer evaluators, then that's a positive step."

She does believe in making some accommodations for community research staff when needed. For example, Campbell's group developed a glossary of research terms to train peer evaluators. Even if the terms don't come up in their duties, they also may serve on an advisory board or other capacity where they're speaking with research professionals and need to know what the terms mean.

DuBois believes that advisory boards are an important tool of community engagement in mental health studies, particularly because IRBs tend to lack sufficient representation on their boards to address the community's ethical concerns.

"My impression is most IRBs don't have even one community member who could represent mental health consumers well," he says. And DuBois argues that having one mental health consumer on the board would still be inadequate, since there are diverse perspectives in this community.

"If you ask me what IRBs might ask of researchers, it's 'Have you created a community advisory board? Have you consulted with people from the community that you plan to recruit from?' It seems to me that that's a good starting point."

REFERENCE

DuBois JM, Bailey-Burch B, Bustillos D, et al. Ethical issues in mental health research: The case for community engagement. *Curr Opin Psychiatry* 2011 May;24(3):208-14. ■

High schoolers getting schooled in protections

Through science fairs, special schools and summer programs, they get experience with IRBs

As high school students get exposed to more sophisticated science and health programs, some are also having their first encounters with human subjects protection issues.

In science fair projects, in special science and health schools and through outreach programs from research institutions, they're doing social and behavioral studies and being taken on to help established scientists with medical research.

While the number is not necessarily large, observers say aspiring investigators already are interacting with IRBs.

Rebecca Dahl, PhD, CIP, manager of the human subjects protection program at Children's Hospital Los Angeles, says she recently was approached about allowing a high school student who was participating in a summer research program to be added to a protocol.

"They wanted to have the student assist them," Dahl says. "And people were wondering what to do and how to go about the proper process."

Dahl says that she would be very cautious about what type of assistance a high school student would be able to provide.

"I would have to determine if what the student is doing is really at the level of knowledge and understanding so that they can perform things where they can feel successful," she says.

Those tasks might actually include interaction with subjects — handing out surveys or answering simple questions — as long as they were closely supervised by an investigator. And she says they would require the same type of training required of older research staff.

"But remember, most of these kids, although they're screened very carefully to even be involved in the summer programs, they're not screened for research knowledge and they don't get that, necessarily, in the high schools."

High school IRB

At some specialty high schools, however, human research ethics is actually part of the curriculum.

Judith Scheppler, PhD, is coordinator of student inquiry and research for the Illinois Mathematics and Science Academy in Aurora. Her students conduct their own research projects, as well as working off-site with established researchers at area institutions such as the University of Chicago, Northwestern University and Fermilab.

The school requires that students working off-site be written into investigators' IRBs proposals and that the school receive a copy of the outside IRB's approval letter.

"We don't want our kids to be used in the wrong way to do data collection," she says. "And we also use it as an educational tool for our students. By getting that (approval), we hope that they understand that you can't just go out and do research with human subjects without oversight."

IMSA also has its own IRB, chaired by Scheppler, in part to deal with student-generated research (It also fields requests from adult investigators wishing to recruit IMSA students for studies). Although the school does not handle federally funded research, Scheppler says the board's policies require that it follow federal guidelines.

"If your students are doing research, one can make the case that they are doing it as an educational endeavor and therefore they don't actually need IRB approval," Scheppler says.

"But for a number of students, it really becomes a gray area. I will have some of my students present at places such as the Illinois Gifted Conference. At that point, they are subject to IRB guidelines, because they are participating in a public venue, contributing to generalizable knowledge."

Scheppler says that about five years ago, the school added a core course for sophomores called "Methods of Scientific Inquiry," part of which deals with human subjects protection issues.

When students submit research proposals, they must provide an ethical overview of their research, and, if it involves humans, must detail how they plan to handle such questions as voluntary participation, confidentiality and informed consent.

Scheppler says some of her students have done observational research in classrooms at other schools, and have quizzed students to gauge the effectiveness of different teaching styles.

"We're really not going to do anything that's more than minimal risk, because our students just aren't skilled enough to take on anything more than that," she says. "And we're dealing with, at least on the campus, non-biomedical research."

But she says students have studied topics such as teasing, where there was some concern about psychological risk.

"What we do is make sure they're working with one of the counselors when they do those surveys, so the counselors are aware if any student becomes stressed because of the nature of the questions."

Science fairs

For many high school scientists across the country, the school science fair can be their introduction to some form of an IRB.

The world's largest international high-school science competition, the Intel International Science and Engineering Fair (ISEF) has requirements for human subjects research that follow federal regulations.

Each participating school that allows human research must establish its own IRB, made up of at least three members including a science teacher, a school administrator and someone who can assess physical and/or psychological risk (a doctor, social worker, psychologist or school nurse can fulfill this requirement).

Nancy Aiello, PhD, chairwoman of Intel ISEF's scientific review committee (SRC), says some schools in larger metropolitan areas can tap local research institutions for IRB members. Students working off-site with an established researcher must have that project approved by the outside institution's IRB.

Local and regional SRCs, as well as her own SRC, which oversees the entire fair, can review decisions of school IRBs. If an SRC believes subjects were not adequately protected, a finished project can be declared ineligible for competition.

The most common concern, Aiello says, are surveys that ask high school students inappropriate questions.

"Kids are always trying to find out information about other kids," she says. "Asking about drug use, about their sexual habits, things like that. In cases like that, you have to make sure that there's been proper review and approval, that parental permission has been obtained and that the parent has seen the copy of whatever instrument was used."

Elaine Labrocca is on the SRC for schools on Long Island, NY, an area well-populated with research institutions and parents who work at them. So she sees a lot of fairly ambitious research projects from students.

"You'd be surprised what some high school kids do," she says.

She says her SRC is conservative about what it will allow. Recently, she notes, it required that surveys and other research being conducted with students not be done in a classroom during class hours. The SRC was concerned about issues of voluntariness.

"The high school population is very prone to pressures from peers," Labrocca says. "And we didn't want it where there was a grade being given. We want (participants) to go where they

have to go voluntarily."

The Long Island SRC also does not allow students to ask other students about illegal activity.

"On a cell phone study, there was a question this year that seemed innocuous. They asked, 'Have you ever used your cell phone while you're driving?' Well that's an illegal behavior in New York," Labrocca says. "That project was deemed minimal risk and so there was no qualified scientist, although I believe they did have consents.

"We allowed it to go through, but we used the opportunity to educate them and we required a letter from their IRB that they are aware that any question that implies an illegal behavior is inappropriate."

Teachers on the front lines

Labrocca says that while some school IRBs have become well-educated about human subjects protection issues, other schools still struggle with it. She has investigated the possibility of requiring one member of each local school IRB to have online human subjects protection training.

Meanwhile, she says, the importance of educating students about these issues lies with their teachers.

Scheppler notes that students are very interested in the types of ethical questions that have historically been raised by human subjects research.

"Talking to students about things like the Tuskegee syphilis study, (Stanley) Milgram's (obedience) studies — kids like that sort of stuff," she says. "They like that human element, that dilemma, that thing that went wrong. I think that's one place where you can bring some of these things to light for them and have a discussion."

Dahl believes there may be a role for IRBs in promoting awareness of human subjects protection issues among high school students.

Before coming to Children's Hospital Los Angeles, she was director of human subjects protection at the University of Arizona, where she began to explore the idea of engaging with high school students in order to interest them in human subjects research.

"My goal was to reach out to high school seniors because they are the ones who may progress to a career in research," she says. "I wanted to go out and do workshops, brown bags, lunch seminars."

When she was recruited to CHLA, the idea was dropped. But Dahl still hopes to pursue it someday. ■

Pediatric pain trials beget novel approaches

Children can't experience more pain through a study treatment than they would in standard care

Researchers say there need to be more clinical trials examining the safety and effectiveness of pain medications used with children, which are too often administered based on information from adult trials.

Gary Walco, PhD, director of pain medicine at Seattle Children's Hospital, says extrapolating from adult clinical data doesn't provide assurance that pain medications are safe for children.

Children often metabolize drugs differently, and there is the possibility that medications, especially those used long-term, may affect development.

Despite the need for pediatric pain trials, Walco says there have been obstacles to conducting them, including a lack of consistent guidance. Now, as a result of a 2009 conference involving the FDA and pediatric pain experts, that obstacle may be overcome.

"A paper has been written that lays out all of these issues so that when (pharmaceutical companies) come to the FDA, they could say, 'Look at this paper, it's peer-reviewed, that's your road map," Walco says.

He says the paper is scheduled to be published later this year.

No greater pain

One ethical issue Walco says is important in conducting a pain trial for children is the idea that pediatric participants cannot be disadvantaged as a function of being in the trial.

"That means they can't endure any more clinical pain than they would in standard clinical care," he says. "For example, if you were (participating in) a placebo-controlled trial, even if it's for one-time acute pain, that's fine if you're an adult and you agree to it. But we would say that you cannot expose a child to more pain."

Walco says it is possible to design trials that meet this requirement. For example, in an opioid sparing trial, patients have ready access to an opioid such as morphine to treat pain. In addition, they would take a study drug or placebo. The effectiveness of the study drug would be measured not by how much pain the child reported, but by how much

morphine had to be used to minimize pain vs. that used with placebo.

He says IRBs reviewing protocols may have to make fine-tuned judgments about the degree to which participation in a study may potentially cause more pain for a participant than standard care. For example, defining standard care may be tricky.

"If you're doing study of needle pain, I can argue that in the year 2011, no child should be stuck with a needle without a topical anesthetic," Walco says. "So I could say that's the standard of care. But you could go to Institution X and they'll say 'What are you talking about? We don't use topical anesthetic for needle sticks in our institution.' The IRB needs to make that determination, as to what is the local standard?"

Long term effects

Walco says other issues IRBs should consider when reviewing pediatric pain studies include:

— Children participating should get some direct benefit from the study.

— Physical and emotional pain should be prevented as much as possible and effectively treated when unavoidable. Physical pain and distress must be monitored appropriately.

— Painful procedures such as blood sampling should be minimized.

— Walco says that in general, pediatric analgesic trials should be conducted in pediatric facilities, because they're most attuned to the needs of children.

He says consent and assent procedures are generally the same as they are for other pediatric trials.

Walco says it's important for pain trials to look not just at the immediate effects of using pain medication, but at the long-term impact, including any effects on the development of children.

"Especially if you're talking about some of the medications that are going to be used for more recurrent and chronic pain, where you're using them over time," he says. "How likely are negative side effects to occur? What is the magnitude of their occurrence? How long might they last?"

Even with the new guidelines for pediatric pain trials, Walco says obstacles remain, including finding enough patients to study. He and other pain experts are starting an international research collaborative to create multi-site analgesic trials for children. So far, 55 centers around the world have expressed interest.

"We hope by setting up a research consortium to do these trials and getting centers on board, they will be more likely to get done," he says. ■

Ethics office supports community researchers

Ontario organization focuses on social science studies

Seeing a need for ethics guidance for local groups attempting to conduct community-based research, an organization in Kitchener, Ontario, has created an independent Community Research Ethics Office (CREO).

The recently launched CREO, housed in an existing community research center, provides guidance for investigators planning projects, as well as online resources and its own research ethics board (REB, the equivalent of a U.S. IRB) to review proposals as needed.

Norah Love, MA, coordinator of the CREO, says it came in response to requests from local community researchers. In 2008, the Centre for Community Based Research, which has served the area for nearly 20 years, invited researchers to talk about the challenges they faced.

"The overwhelming response from that meeting was that there is a need for more support in our region for community-based research," Love says. The center launched a needs assessment and feasibility study and brought back a proposal for the formation of a CREO in 2010.

Researchers assisted by the CREO will include those from not-for-profit organizations or independent consultants conducting social science research. Projects also can include activities not always seen as research, such as program evaluations and needs assessments. **Bill Marr**, PhD, chairman of the REB at nearby Wilfrid Laurier University and now the CREO's REB chairman, says Canadian regulations do not cover these types of activities.

"Although there is privacy legislation in Canada, there's really not legislation either at the federal or provincial level that covers what you and I would understand as the ethical norms of collecting information from people," Marr says.

Unaffiliated researchers

In Canada, research conducted through an institution that receives funding from government agencies would require the use of an established REB. But the CREO notes that research is increasingly being conducted outside of these types of

institutions.

Unaffiliated groups say they want support on ethical issues without having to partner with a university or other institution to get it, Love says.

"People want to have review of a project for their own quality assurance purposes," she says. "They want partnerships for the sake of partnerships as opposed to partnerships for the sake of having a review."

The CREO provides support in a number of ways, depending upon the researcher's needs. A consultation service can help identify potential ethical issues with a project and guide the researcher in addressing them. The CREO can provide training sessions or workshops for researchers and community members involved in studies. If the researcher wishes, he or she can submit a proposal to the CREO REB for a formal review. And a website (www.communityresearchethics.com) provides links to useful information about ethical issues.

"One thing that was quite evident from community forums was that organizations wanted a website where they could go and find information about things like how to undertake community-based research, how to do it ethically," Marr says.

Love says there are many sets of guidelines available, but no complete agreement as to how to handle these issues.

"There's no one set of guidelines they can go to to learn how to train community researchers, for example," she says. "They have to sift through so many resources and they don't have a clear understanding of what the best practices are. (Researchers) are hoping to have a place or a group in the community that can help be a consistent voice for community-based research and how to conduct it."

In addition to Marr, there are 10 other members of the volunteer REB, including those with experience as researchers, former participants and those with REB experience. "We wanted to have a multidisciplinary mix," he says.

Researching the research needs

A major strength of the CREO's approach is that it did its own community-based research before going forward with a plan, Love says. She says other communities in the U.S. and Canada who are interested in the idea should not skip those important steps of engaging the community to be served and listening to their concerns and suggestions upfront.

"We really did model community-based research in the development of a community research ethics office," she says. "The idea is that if we're developing something collaboratively, then hopefully it will be of use to the people who developed it in the first place."

One challenge for the office will be funding. Its pilot year has been funded by a grant from an Ontario government foundation, but Love and Marr are unsure where continuing funding will come from. ■

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 continuing education program and earn credit for this activity by following these instructions.

1. Read and study the activity, using the provided references for further research.
2. Log on to www.cmecity.com to take a post-test; tests can be taken after each issue or collectively at the end of the semester. First-time users will have to register on the site using the 8-digit subscriber number printed on their mailing label, invoice or renewal notice.
3. Pass the online tests with a score of 100%; you will be allowed to answer the questions as many times as needed to achieve a score of 100%.
4. After successfully completing the last test of the semester, your browser will be automatically directed to the activity evaluation form, which you will submit online.
5. Once the completed evaluation is received, a credit letter will be e-mailed to you instantly. ■

COMING IN FUTURE MONTHS

- Conduct a quality assessment of IRB reviews
- Approving enrollment of pregnant women requires careful work
- Improve personnel decisions following these strategies
- Ethical considerations in pediatric pain research
- Community engagement in mental health research: Challenges and opportunities
- IRBs for high school researchers? It's already happening
- Community research ethics office established in Canadian community
- The latest on ownership of human research specimens
- Update on the National Children's Study: What have we learned about pediatric research?

CNE/CME QUESTIONS

Please note: *There was an ommission in the July 2011 issue of* IRB. *CNE/CME questions 27 & 28 were inadvertently left out of the issue. Questions 27 & 28 are included below, but refer to content in the July issue. Please see the July* IRB *articles in your printed issue or in the online version of July 2011* IRB *by logging in with your subscriber number at* **www.ahcmedia.com.**

July 2011 IRB CNE/CME Questions *(please refer to articles in the July 2011 issue)*

27. In surveys of genetic researchers and IRB professionals which of the following was NOT identified as an issue that required "considerable in discussion" during review of genetic research:
    A. When to reconsent subjects who had previously given a sample if it was used for a new study or research purpose.
    B. Return of research results to participants
    C. Recruitment strategies for genetic research
    D. Potential for reidentification of subjects

28. True or False: 96 percent of all subjects with schizophrenia who participated in the CATIE study saw improvements in measures of their capacity to give consent.

August 2011 IRB CNE/CME Questions

29. According to the administrative director of the Case Cancer IRB at Case Western Reserve University, School of Medicine in Cleveland, the benefit to having an IRB that specializes in a particular area, such as a cancer IRB, is which of the following:
    A. It can reduce duplication
    B. It can improve protocol turn-around time
    C. It gives investigators and clinical trial staff an IRB office that understands and caters to their specific questions and concerns
    D. All of the above

30. An IRB desk manual can be used by new and interim staff when a key IRB professional or manager is on sudden leave of absence. Which of the following details is not a topic that could be covered in such a manual?
    A. What type of letterhead is used for approval letters?
    B. Where are the examples of continuing review letters?
    C. Which instances should result in a survey research protocol being rejected by the IRB?
    D. What should be done if someone calls to ask if their project qualifies as human subjects research?

31. True or False: Children participating in a pediatric pain trial should not be exposed to more pain than they would under standard clinical care.

32. Which two of the following are among the research priorities of mental health consumers?
    A. Decisional capacity
    B. Fair compensation for participants
    C. Undue influence
    D. Side effects of medications