IRB ADVISOR

Your Practical Guide To Institutional Review Board Management

April 2014: Vol. 14, No. 4
Pages 37-48

IN THIS ISSUE

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Preliminary review reaps quick benefits for health system IRB

Deferrals dropped 30% in three months

A large health system IRB found that incomplete study submissions were clogging up the IRB review system, resulting in long waits — up to three months — for approval.

More than 40% of IRB submissions were deferred for substantive issues, says **Dorean J. Flores**, CIP, IRB manager, North Shore-Long Island Jewish (LIJ) Health System in New Hyde Park, NY.

With 2,100 open studies that the IRB reviews, the high deferral rate was causing long delays in IRB approvals and wasting staff time, she notes.

Also, the IRB's workload was growing. Prior to 2013, the IRB office had two IRB committees to oversee. Last year, a third committee was added, says **Hallie Kassan**, MS, CIP, director of the office of the human research protection program at North Shore–LIJ.

The IRB solved these issues by developing a thorough preliminary review process, Kassan and Flores say.

Within three months of initiating the preliminary review process, there was a 30% reduction in the deferral rate of initial full board studies.[1]

Also, the turnaround rate on study approvals dropped from three months to 1.5 or two months, Flores says.

"We looked at how we could review effectively without having to hire a lot of staff and how to get protocols reviewed and approved in an efficient manner," Flores says. "We're very customer service-oriented and wanted to cut down on our turnaround time, and we wanted to mitigate any substantive issues that would result in the study being deferred."

The pre-review process has case managers reviewing studies two weeks prior to a convened IRB meeting. The case managers' comments and concerns are sent to the IRB reviewers and principal investigators. The purpose is to aid reviewers' evaluation of the study prior to the full board meeting. Also, the principal investigator is given enough time to resolve issues before the meeting.[1]

"The way the IRB office operates is if a study has the minimum requirements for a full review, it's put on the agenda even if it would result in a deferral," Flores says. "These deferrals were sent back to investigators."

The main purpose of the preliminary review process is to decrease time to IRB approvals and to decrease work on both sides, Kassan says.

"It makes us more efficient," she adds. "First of all, it makes the IRB meeting minutes easier to write."

When case managers find problems with a study submission that would result in a deferral, they contact the investigator and obtain additional information prior to the IRB meeting, she explains.

"Having these answers ahead of time saves time at these meetings," Kassan says. "If we can avoid deferrals, then the study doesn't have to come back to the full committee for a re-review, and it saves IRB members' time."

Kassan and Flores describe how the project works:

• **Assign cases to IRB case managers.** The IRB office divides the pre-review workload to fairly distribute it.

"We have five IRB case managers, and those five case managers have specific departments that they oversee," Flores says. "Not all of these departments submit studies every month, so we balance the workload so everyone has a study to review."

If a case manager has a light caseload one month, then she or he might pitch in to help another case manager, she adds.

• **Implement a pre-review process.** The IRB started the pre-review process in 2013, Flores says.

IRB case managers review the protocol, informed consent form, sponsor documents, and other sections of the submissions, looking for major issues that could result in a deferral, she explains.

They spend about three hours on more complex, sponsor-initiated studies when they are conducting the pre-reviews, she adds.

"We look at whether the risks are minimized," Flores says. "We look at every major issue that would have prevented it from being approved or contingently approved."

Other questions a pre-review covers include:

- What are confidentiality protections?
- Is there an appropriate risk-benefit ratio?
- Are we protecting vulnerable populations?

"We want answers to each and every item that needs to be addressed," Flores says. "If we have a basic answer that is not as detailed as possible, then we communicate that concern to the investigator."

• **Send comments to IRB reviewers and investigators.** "We send our pre-review comments and documents to the IRB reviewers about 1.5 weeks before the meeting, so they'll have a week to look at the documents," Flores says.

They also send their findings to investigators and request a fast turnaround on responses so that

IRB Advisor (ISSN 1535-2064) is published monthly by AHC Media LLC, One Atlanta Plaza, 950 East Paces Ferry Road NE, Suite 2850, Atlanta, GA 30326. Telephone: (404) 262-7436. Website: www.ahcmedia.com. Periodicals Postage Paid at Atlanta, GA 30304 and at additional mailing offices.

POSTMASTER: Send address changes to IRB Advisor, P.O. Box 550669, Atlanta, GA 30355.

Subscriber Information

Customer Service: (800) 688-2421 or fax (800) 284-3291. E-mail: (customerservice@ahcmedia.com). Hours of operation: 8:30 a.m.-6 p.m. Monday-Thursday; 8:30 a.m.-4:30 p.m. Friday, EST.

Subscription rates: U.S.A., **Print:** 1 year (12 issues) with free *AMA Category 1 Credits*™ or Nursing Contact Hours, $419. Add $19.99 for shipping & handling. **Online only, single user:** 1 year with free *AMA Category 1 Credits*™ or Nursing Contact Hours, $369. Outside U.S., add $30 per year, total prepaid in U.S. funds. Discounts are available for group subscriptions, multiple copies, site-licenses or electronic distribution. For pricing information, call Tria Kreutzer at 404-262-5482. Back issues, when available, are $75 each.(GST registration number R128870672.)

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Editorial Questions

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these also can be given to IRB reviewers, Kassan explains.

"Sometimes the investigator responds close to the meeting time, and we bring the response with us to the meeting and discuss it with the committee," Kassan adds.

Typically, investigators have two or three days to respond to questions and comments, Flores says.

"Investigators have been very responsive to us, and they might send a quick email to clarify additional issues," she adds.

• **Adjust the program when obstacles appear.** When the IRB started the pre-review process, the staff found that the first three months were the most difficult because case managers were not receiving timely answers from investigators, Flores says.

"We crunched numbers and ended up with six deferrals in one meeting, and it wasn't working," she recalls.

Something had to change. "The pre-review process won't work if investigators don't know to look for a quick email from us within the first two days of submission," she explains. "So we spoke with research coordinators, who are the eyes and ears of the study."

They told the coordinators to watch for an email from the IRB and to make certain the email's questions and comments were answered immediately.

"We email research coordinators directly and cc [carbon copy] the investigator," Flores says. "We let them know that when they are having a full board review they will get pinged by us for a couple of days, and so they need to look for those emails."

Once the IRB office began to work more closely with research coordinators, the rapid response rates greatly improved, Flores notes.

Another obstacle involved the IRB reviewers' perceptions of the pre-review.

During the first few months of the pre-review process' launch, IRB case managers were reviewing all the issues, including those that were not necessarily deferral issues, Flores explains.

As a result, some IRB reviewers felt the case managers were doing their work for them, Flores notes.

"This caused a bump in the road," she says.

The IRB office resolved this by having the pre-review focus on issues that could result in a deferral and leaving the big issues and scientific issues for the IRB reviewers, she adds. "We had to tweak the pre-review process to not review everything."

The last change was to do a better job of letting IRB reviewers know more about the pre-review process and what to look for in the information sent their way, she says.

• **Reduce IRB office and staff workflow.** The IRB office has made staff workflow much more efficient since the pre-review process began and deferral rates dropped, Flores says.

"Overall, we could have needed seven to eight people to handle 2,100 studies," she says. "Now that we have this efficient process going on, those studies are coming in and reviewed in a manner to address all concerns and only leave minor issues."

This leaves a reduced burden on IRB committee and staff to get everything ready to bring to the committee, Flores adds.

"The initial time we spend in the beginning with the pre-reviews actually saves time in the end," she says.

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1. Flores DJ, Ramdeo R. Comparative study on the effectiveness of a preliminary review process in the reduction of study deferrals. Poster presented at the 2013 Advancing Ethical Research Conference, held by the Public Responsibility in Medicine and Research (PRIM&R), Nov. 7-9, 2013, in Boston. ■

IRB develops non-research QI templates

Policy charges IRB with determination

Academic and medical research institutions and their IRBs often have to deal with study proposals that fall between research and quality improvement (QI). The solution is an initiative that addresses QI projects separately, experts say.

This issue was particularly difficult at one major university where nurses often conducted QI projects that they tried to fit into the research template.

Nurses were trying to put their QI projects into a research-based template and then they'd submit these proposals to the IRB, explains **Marilyn Hockenberry**, PhD, RN, PNP, FAAN, Bessie Baker professor of nursing, professor of pediatrics, and IRB chair at Duke University in Durham, NC.

"The IRB chairs would evaluate them and find all kinds of things wrong with them because they were quality improvement projects and not research," Hockenberry adds.

"There has been a great debate about that slippery slope of QI and research, and we've spent many hours of discussions about this gray area," Hockenberry says. "So it's opened up a dialogue across the campus, and it's caused great awareness and lots of interest."

The result is a new policy about QI activities in healthcare vs. research, which states that a QI project does not need to be submitted to the IRB. The policy also states that Duke students, trainees, and faculty who are conducting QI projects must submit to the IRB for an authoritative determination of whether the activity meets the definition of research with humans.

When investigators have a QI project, they can apply for an exemption from further IRB review. The IRB created a QI vs. research checklist to assist them with identifying QI activities. *(See checklist box, below.)*

In light of a national trend to clear IRB agendas of non-research submissions, the IRB initiated a project to help students and faculty determine which projects could be classified as quality improvement and which were research proposals that needed to be submitted to the IRB.

"This was a problem for many of our graduate students at Duke who wanted to do QI projects," says **June Walker**, MS, MSCR, CIP, IRB compliance specialist at Duke University Health System IRB.

The problem was that IRB submission forms were not asking the right questions, and not well-suited to distinguishing between nontraditional research and QI projects, Walker notes.

Tackling this problem began with gathering IRB leaders to discuss making a change, Hockenberry says.

IRB leaders readily agreed to consider making changes, she notes.

"It helped tremendously to have the Hastings published report last year," Hockenberry says. "Once everyone said 'yes,' we had more facilitating meetings, and we decided to draft a proposed policy."

The Hastings Center's *IRB: Ethics & Human Research* journal published an article in the fall

Duke University's checklist for QI activities

Research vs. QI checklist

Duke University's IRB in Durham, NC, uses a checklist, adapted with approval from a similar checklist developed by the Yale University IRB, to help students, faculty, and others determine whether their project meets the criteria for human subjects research or is a quality improvement (QI) project. Its nine questions must be answered with a "yes" for the project to be a QI activity and not require an IRB review.

Here are the nine questions:

- **Purpose:** Is the activity intended to improve the process/delivery of care while decreasing inefficiencies within a specific healthcare setting?
- **Scope:** Is the activity intended to evaluate current practice and/or attempt to improve it based upon existing knowledge?
- **Evidence:** Is there sufficient existing evidence to support implementing this activity to create practice change?
- **Clinicians/Staff:** Is the activity conducted by clinicians and staff who provide care or are responsible for the practice change in the institutions where the activity will take place?
- **Methods:** Are the methods for the activity flexible and include approaches to evaluate rapid and incremental changes?
- **Sample/Population:** Will the activity involve a sample of the population (patients/participants) ordinarily seen in the institution where the activity will take place?
- **Consent:** Will the planned activity only require consent that is already obtained in clinical practice, and could the activity be considered part of the usual care?
- **Benefits:** Will future patients/participants at the institution where the planned activity will be implemented potentially benefit from the project?
- **Risk:** Is the risk to patients/participants no greater than what is involved in the care they are already receiving, OR can participating in the activity be considered acceptable or ordinarily expected when practice changes are implemented within a healthcare environment? ■

about differentiating between clinical research and quality improvement.[1]

The result was a template, which was piloted in January 2013. It's a Word document that is attached to an applicant's electronic submission to the IRB. They start by picking up the template from the IRB website. Then they complete the form and submit it electronically in the university's e-IRB electronic submission system. Applicants have to select the pathway for an exemption review, and the IRB makes an exempt determination, Walker says.

"You submit it to be exempt, but the IRB decides if it's exempt," Hockenberry says.

The QI template asks for a letter of support or administrative approval from the clinical site where the project will occur, and it requests this information:

- project title and clinical site;
- statement of the problem;
- evidence — literature review and synthesis;
- project aims;
- project methods;
- data collection plan;
- timeline;
- evaluation plan;
- protected health information; and
- privacy, data storage and confidentiality.

An instruction sheet offers explanations for each of the items on the form. For instance, under the project aims, the instructions say, "Identify the purpose of this project and list specific aims or goals to be accomplished. The aims should clearly support that the project is to implement evidence into clinical practice (quality improvement) and that it will not produce new knowledge (research)."

The instructions also ask applicants to describe how the QI project will be evaluated and what statistical measures will be used.

"We piloted it for three months with graduate students," Hockenberry says.

A senior IRB chair reviewed the completed templates to catch mistakes, she adds.

The IRB's goal was for the template to be used appropriately — with exempt QI projects, she says.

It appeared to achieve that goal, so they rolled it out systemwide. Anecdotally, feedback indicates that students find it easy to use, Hockenberry says.

"Everyone says it's so easy to use because it works," she adds.

Duke's residents are also interested in the process, Walker notes.

"Young physicians commonly do QI projects, and the medical students in our medical school often conduct QI projects in their third year of medical school," she adds.

While this project started out as a solution for the nursing school, it's now used across the Duke campus, Hockenberry says.

"I think it's a time saver for the IRB," she adds. "It still has to come to the chair, but I think what happens is you don't spend so much time trying to get them to reword things because we're trying to fit it into a research study. It's now straightforward, and they're much more easy to review, evaluate, and identify an exemption."

REFERENCE

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BEST PRACTICES SPOTLIGHT

Research institution revamps HRPP training

NIH updates education FAQs

Human research protection programs (HRPPs) receive only general guidance on how they might fulfil their educational requirements, so programs range from simply requiring research staff to complete online courses to institutions that offer a broad smorgasbord of educational options.

The National Institutes of Health recently updated its educational information for human subjects research (HSR), highlighting the importance of providing HSR education to all key personnel involved in human subjects research.

NIH's frequently asked questions (FAQs) emphasize the need for all individuals involved in NIH-funded HSR to fulfil the education requirement. This applies even to subcontractors, consultants, and staff who do not receive compensation from the NIH award, according to the FAQs updated Dec. 12, 2013.

The NIH leaves the curriculum and any continuing education requirements up to each research institution's discretion.

So where can IRBs and research programs find the optimal training program?

One model is from the Indiana University School of Medicine in Indianapolis. The institution recently revamped its research education program, providing comprehensive training and education opportunities to all research coordinators, from first hired to experienced personnel, says **Jody Harland**, MS, CIP, program manager, regulatory knowledge and support, Indiana Clinical and Translational Sciences Institute (CTSI), pediatric clinical and translational research, Indiana University School of Medicine.

The institution's new program has four levels of education with ongoing program evaluation efforts. Average evaluation scores for Level One training were 4.78 on a 5-point scale.[1]

"The first thing we did was make sure whatever programming we developed would be something people would be interested in and want to attend," Harland says. "Part of our goal was to enhance a couple of existing programs for coordinators."

Here are the steps they took in revamping their education and training program:

• **Create a task force.** In 2012, when the university's HRPP decided to create a more centralized education and training program, they created a multidisciplinary task force, Harland says.

"We thought it had to be a team approach to be the most effective, and we have a lot of stakeholders inside the human research protection program," Harland says.

The task force included a number of interested parties, including representatives from the CTSI, the university's office of research compliance, and the local Veterans Affairs Medical Center.

Task force members serve as consultants, providing expertise as needed.

"We still go to them when we have a question or consideration involving their areas [of expertise]," Harland says.

The task force reviews and conducts annual evaluations of the program. Also, the task force collaborates with the HRPP.[1]

• **Start with Level 1 training.** The task force created a new program for entry-level coordinators. Offered monthly, it is mandatory for some research staff.

"That was the first program we focused on developing," Harland says. "We used survey data we had collected from staff in the school of medicine to develop what we wanted to cover in some of these areas."

They also worked with the university's human resources office and arranged to have the HR office send them a monthly list of new research coordinators, she adds.

The new hire training program is held monthly in a two-hour session. The program is capped at 12 participants and is intended to be informal and to facilitate conversations, Harland says.

Trainers include Harland, a representative from the HRPP office, and two experienced coordinators.

• **Add Level 2 training.** This stage of training is geared toward beginning research coordinators and is meant to enhance their existing training. It's offered semi-annually and covers the basics of clinical research.[1]

• **Offer Level 3 training for mid-level staff.** The third level provides training for mid-level research coordinators, and it's also offered semi-annually. Its purpose is to provide more in-depth information of clinical research topics.[1]

The Level 3 program was created to enhance existing educational programs, Harland notes.

"But we revamped it pretty heavily," she says.

Attendees include staff with three or more years of experience. It's a two-day course. While the course isn't mandatory, continuing medical education credits are offered, she adds.

"We talk about the IRB and some hot topics in research budgeting and billing," Harland says. "We talk about quality assurance and improvement activities that you can implement in your own shop."

Other topics include time management and project management.

"We have a journal club hour where we distribute a journal article about the role of the research coordinator, and we have people read that and then come back the next day to say how they fit into this picture," Harland explains.

At the first Level 3 session, 17 staff members attended, she adds.

• **Expand to Level 4 for experienced staff.** The final level of training is offered to experienced coordinators, research administrators, and research managers. It's a high-level, annual program.[1]

The Level 4 education is continuing to be developed, Harland says.

"We hope to launch it in 2015," she adds. "The concept is that once we get folks trained and they're in research for at least five years, then we want a session that is for much higher-level folks."

The annual, one-day program would have speakers from within and outside the academic medical college, and it would be a voluntary educational choice, she says.

CME would be offered, and attendees would need to have a professional certification in clinical

research coordination, such as a CIP, or a research coordinator certification, Harland says.

"We recognize that there are a lot of people who have knowledge and expertise and are out in departments where we don't have a lot of ways of sharing best practices and information," she explains. "These sessions could have best practice sharing and promote that kind of interaction."

• **Incorporate informed consent and other hot topics.** The research coordinator topics include the IRB and informed consent and HIPAA privacy, as well as other topics that often draw questions from research coordinators, Harland says.

"One topic everyone says they want to hear about is HIPAA and privacy," she adds. "That's important, but there were other topics that resonated more with coordinators."

For instance, coordinators wanted to learn more about quality and data management and what resources were available on campus, she says.

They were interested in the IRB and regulatory issues, but less interested in the finance and contract side, Harland says.

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Short form translation saves time, costs

Experts also say it can increase enrollment

Translation of full informed consent forms into other languages can be a costly and time-consuming endeavor for researchers, particularly if there are few non-English speaking participants in a study. To ensure the equitable and diverse enrollment of subjects, many research institutions use short form consent, a brief form that describes the elements of informed consent in the subject's native language. Short form consent can help ensure that a greater number of subjects have access to a clinical trial.

"People come here from all over the world [for treatment]," says **Heather Cathrall**, MBE, CIP, assistant director, IRB Operations at The Children's Hospital of Philadelphia (CHOP). "We wanted to make sure that the subject selection was equitable and they had access to the trials we have."

For studies with a very small number of non-English speaking subjects, translating the entire consent form became a time and cost burden to researchers. CHOP introduced the short form consent process to alleviate the cost burdens and ensure that a greater subject population could be enrolled in studies.

The short form contains brief explanations of all the elements of the consent form, including what the study entails, risks and benefits, etc., in the participant's native language. An interpreter from CHOP's Language Services department reads the consent form to the participants (in the case of CHOP, to the parents or guardians of the participant), and the study team is present to answer questions. When everyone feels comfortable that the participants understand the study and what to expect, the interpreter and the participants sign the short consent form, and the study team and interpreter sign the English version of the form.

At first, the institution's interpreters were hesitant to sign the short forms due to the wording. "One of the struggles we had until recently was that, even though the study summary documents were IRB approved, the interpreter would say they did not want to sign the form because they didn't feel comfortable," says **Amy Schwarzhoff**, BS, CIP, director of human subjects research at CHOP. The vice chair of the Committee for the Protection of Human Subjects collaborated with representatives from Language Services to craft consent form language that was acceptable to everyone. "Everyone felt that it met the requirements of the consent process and wasn't over-promising anything," she says. *(For examples, see box on page 44.)*

The documents are already IRB-approved, so an investigator does not have to seek an amendment for an approved document if it must be added. The language of the short forms is generic, and the form includes spaces for investigators to add names, contact information, study name, and other required information. Because the forms are already approved, permission can be given quickly if the need for a form arises.

"Every once in a while, there will be a study team who didn't anticipate these participants and didn't get approval ahead of time [to use the short form]," Schwarzhoff says. "We can usually turn the request around in a couple of days."

When a researcher encounters a subject who speaks a language not already in the form database, he or she will use the available resources to have the English form translated. Though there is some initial cost, it is more manageable than translating an entire consent form — and can greatly expand future study subject pools. "There is some cost with the translation, but when the form is used in 200 studies, it can expand your subject pool," Cathrall says.

"It [short form consent] makes adding new subjects a lot faster and less labor intensive," Schwarzhoff adds. "It also makes reviewing studies quicker than it would be otherwise."

Researchers from the University of Pennsylvania also use short form consent. If a researcher enrolls a study participant who speaks a language for which there is not already a form, he or she can request to have the English short form translated, and the new form is kept on file. If a particular researcher submits many requests for a particular short form, he or she is then asked to translate the entire consent form. "We don't require the entire translation when it's an incidental enrollment of the [non-English speaking] subject," says **Tracy Ziolek**, MS, CIP, director of Human Research Protections at the University of Pennsylvania in Philadephia.

One of the biggest issues with the consent process when using the short form, she says, is mak-

Examples from CHOP's short consent form

The Children's Hospital of Philadelphia (CHOP) IRB uses a short form consent process for the incidental enrollment of non-English speaking research subjects. The English version, found below, includes the name of the protocol, the investigator's name and contact info, and emergency contact info. The following elements are also included:

You are being invited to participate in a research study.

Before you agree, the investigator must explain a number of things to you. These things include:

- The purpose of the study.
- How many people will be enrolled in the study and how long the study will last.
- The tests, procedures, or treatments that will be done.
- Which tests, procedures or treatments are experimental.
- Any risks from the study. There may be risks from a study drug or device, or from a study test or procedure.
- If the study will benefit you in any way.
- How you will be told if there is new information about the study that could affect your decision to continue with the study.
- Other options you have rather than participating in the study.
- What to do if you are injured or hurt during the study.
- Whether there are any costs to you for participating.
- Whether you will be paid anything for participating.
- Reasons the investigator may halt your participation in the study.
- Who can see or use information about you from the study.
- How your information and privacy will be protected.

Witness/Interpreter

By signing this form, you are indicating that

- The information in the Summary Document as well as any additional information conveyed by the person obtaining consent was presented to the subject in a language preferred by and understandable to the subject; and
- The subject's questions were interpreted and the responses of the person obtaining consent were presented in a language preferred by and understandable to the subject.
- At the conclusion of the consent conference, the subject was asked in a language preferred by and understandable to the subject if s/he understood the information in the Summary Document as well as any additional information conveyed by the person obtaining consent (including responses to the subject's questions) and responded affirmatively. ■

ing sure the subject is comfortable with the process and that he or she understands what is going on.

"For me the most important piece is the documentation of the consent witness stating if the process was rushed, if the subject understood it all, etc. If there were any roadblocks to consent, that is going to affect the relationship," Ziolek says. "The short form is just the anchor form — informed consent still needs to occur."

Ziolek offers these tips for developing a short form consent process.

• **Decide on the wording.** First things first, Ziolek says, everyone must agree on the content for the English version of the short form. Investigators, IRBs, study subjects, and everyone involved should be comfortable with the document's wording.

• **Look to other institutions for inspiration.** If you're not sure where to start, see what other institutions are doing. "I would say that if you're starting from scratch, the best thing to do is contact a colleague at another institution; institutions are usually open to sharing information," Ziolek says. "If another institution asked, I would say 'Help yourself' — it's a collaboration among all of us." Make sure that the wording is appropriate and captures the information your IRB wants to capture.

She also recommends sharing foreign language translations of the short form. The form describes the consent in general terms, and the general information — contact numbers, investigator names, study title — can always be changed, she says. "The short form doesn't have the most argued-over language; there's no language on injury or other things people get tripped up over," Ziolek says. "That's why I think it's easier to share forms of this nature, because they don't have the specifics in them."

• **Educate researchers on the process.** The biggest potential roadblock to consent, Ziolek says, is the researcher or subject not having all the pieces of the consent puzzle. If a researcher is not aware of these resources, there may not be a translator provided, or the consent process may not be fully documented. "There's a disconnect with people who are not familiar with it [the process]," she says. "Case by case, we walk them through what is required for their circumstances, and we'll tell them what pieces of the puzzle are missing. The Penn clinical manual is also quite helpful with utilizing the forms."

Education is also one of the pieces of the puzzle, Ziolek says. "I would hate to think someone missed out on participation because the researcher didn't know what they could do," she says. "Knowing that it's an available option and knowing how to use it are two big pieces of education." ■

Expert tips for retaining community members

Education, training are key

Federal regulations require IRBs to include at least one non-affiliated, non-scientist member on the boards, commonly known as the "community member." This requirement is designed to bring in members who are not affiliated with the university, have nonscientific concerns, and represent community rather than institutional interests. Because community members are often not scientists and are unfamiliar with medical terminology, IRBs can run into difficulties finding and retaining community IRB members.

"Getting people to join a board that meets for three or four hours, and uses medical jargon such as 'therapeutic misconception' and 'double-blind placebo' can be a real challenge," says **Charlotte Coley**, MACT, CIP, director, IRB Educational Programs, Duke University School of Medicine IRB in Durham, NC. "Depending on how your board membership categories are set up and thus your quorum, it can be a real challenge. If you don't have the non-scientist member present, you can't have the meeting."

Non-scientist community members can also feel intimidated when surrounded by physicians when they first join an IRB. Learning the lingo and the regulations can feel like a daunting task when everyone else in the room is perceived to already have a handle on things.

"I truly don't think any of them feel confident at first," says **Susan Rose**, PhD, executive director in the Office for the Protection of Research Subjects at the University of Southern California in Los Angeles. Rose says community members may feel even more anxious if they are immediately inundated with federal regulations and institutional policies. "I think that's fine for later, but it's intimidating," she says.

Finding and bringing in willing, motivated community members can be a challenge for institutions. The IRBs at USC mainly rely on word of mouth. "People know and recommend other

people," Rose says. Occasionally the IRB will seek out certain qualifications needed by the board; for example, Rose called around to find a prison representative to be on the board. Otherwise, "I don't think there's any way for them [IRBs] to advertise," she says.

"Collocative" approach

A problem at Duke University arose several years ago when the IRB was trying to attract and classify new community members. There were Duke-affiliated non-scientists who expressed interest in joining, as well as non-affiliated, retired scientists. "The Duke community has a lot of retirees and professionals who want to remain intellectually active and serve and stay engaged," Coley says. "We had people like that, but no membership slot to put them in. We needed an all-encompassing category to include scientists, non-scientists, affiliated, and non-affiliated members." The policy was to staff the IRB with one member from each of the 18 clinical departments at Duke, plus one person from the theology department, and one community member. This became a problem when the clinical IRBs grew to eight, Coley says.

The category of collocative members was created to include any four combinations of members: affiliated scientist, affiliated nonscientist, unaffiliated scientist, and unaffiliated non-scientist. Coley and colleagues chose "collocative" because it is defined as "the act of...placing together with, or side by side with, something else," according to a 2011 journal article by Coley and colleagues.[1]

All new members at Duke attend their first meeting as observational, non-voting members in order to get a sense of the meeting process, and get their first primary reviewer protocol after three or four meetings.

Focus on education

The world of IRBs can be foreign and intimidating to members who have never heard the highly technical medical jargon. Community members are more likely to stay on the board longer if they have comprehensive, ongoing education and training, Coley says.

"At one point, I surveyed the members and asked them how long it took to feel comfortable. Those who didn't have orientation reported it took them about a year to be comfortable, while those who did said it took about six months," she says. "It made a huge difference in people deciding not to give up after a year and stay on the board. We have some members who have stayed on for five or 10 years."

At USC, Rose helped develop a resource manual for new USC IRB community members called, "What it Takes to be an IRB Community Member." The booklet, developed six years ago and updated last year, was inspired by one of USC's long-time community members. "When I first came in [10 years ago], there was no training, just observing some meetings," says **Malena Avila Hough**, a teacher and a long-time member of the USC IRB. "Until I did my first review, I didn't really know what I was doing. I started keeping a notebook and writing down standard rules, terms — anything that could be helpful." When new community members joined, Hough would make copies of her notes and give them to the new members in binders, along with samples of forms. Rose based the resource manual on Hough's need to keep a notebook.

The manual, used nationally, is available online as a PDF file and is divided into two parts: The Basics and Regulations. The Basics outlines what an IRB is, what the community member's roles and responsibilities entail, how to navigate full board meetings, different types of protocol submission and review, and tips for effective protocol review. The Regulations section defines ethical standards, and gives more detail on types of review, informed consent, and what the federal regulations require. There are also appendices that include a glossary of terms, reviewer checklists, and samples of forms, templates, and IRB minutes. The manual can be found at https://oprs.usc.edu/files/2013/05/Community-Member-Booklet-5.1.13.pdf.

USC also requires its community members to take four CITI modules. "Instead of overwhelming them with huge amounts of regulations, we have them do CITI training and give them only easy projects to review initially," Rose says. The IRB also provides mentoring.

The Duke University IRBs have offered a variety of programs: continuing education, mentorship, and a monthly drop-in session where members can discuss any questions they have. There is also a monthly lecture series on various IRB topics and issues, and the lectures are recorded and posted on a password-protected website if members are unable to attend in person. The website also contains PowerPoint orientation modules on the IRB process, regulatory requirements, ethical

standards, and institutional practice; copies of current and past educational presentations at IRB meetings; workshops, website links, and a membership directory.

Both institutions send community members to national conferences, such as the Public Responsibility in Medicine and Research (PRIM&R) annual conference. "Over the years we would take one or two [members] to the national meeting and they were able to network with other community members," Coley says. "PRIM&R now has a track for non-affiliated IRB members so they can get some additional training. They have found that really helpful; it placed value on their role and helped make them understand the big picture of what we do and want to stay on the board longer."

"That's really where they [community members] go to get re-energized and refueled and hear the speeches they need to be able to get back and jump in," Hough adds. "It's a great place to find other members to get energized and learn the backbone of what the role is. We hear people from all over the country about the importance of the role. After the national meeting, I'm energized and ready to jump back in again."

Both Rose and Coley say their institutions benefit from having multiple community members on each board. "Always have one or two more than you need, and don't start the meeting unless at least one is present," Rose says.

Collocative, unaffiliated members make up about 20% of the boards at Duke, Coley says. If there are at least two non-scientist collocative members on the board, there is always one present if the other has an emergency. Currently, there are about three or four members. "I think one of the key things is having more than one [community member] on each board," she says. "If you have a small board, then I understand there will only be one or two. If you're at a larger institution, then you can have three or four on the board and give them some comfort of not being the lone outsider and thus feel emboldened to speak out."

It also makes those members feel less alone, she says. "It produced strength in numbers — there isn't just one lone non-Duke member. It makes them feel more a part of the group and more engaged with the board," she adds.

Some community members may think they are not knowledgeable enough to speak up during meetings.

"I was fortunate to have a very good chair who doesn't shy away from moments to educate," Hough says. "If some of us are completely lost, he'll stop and do some teaching."

There are no dumb questions at an IRB meeting, Coley adds. "At orientation I would encourage all the members to speak out. If you can identify a potential risk to patients, you have done your job. You don't want to see a headline that someone died or was harmed on a study. I tell people if something is bothering you or you're

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. Scan the QR code below or 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

- Research hospital develops user-friendly IC template
- An innovative way to educate IRB members
- IRB redesign eliminates hard stops and delays
- Managing incidental research findings

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curious or it doesn't feel right, speak up. If you're feeling uneasy, someone else may be feeling the same way."

REFERENCE

1. Coley C. Solving the IRB "Community member" problem. *Journal of Clinical Research Best Practices*, August 2011. http://firstclinical.com/journal/2011/1108_Collocative.pdf. ■

CNE/CME QUESTIONS

1. According to Dorean Flores, CIP, which of the following is a good question to ask during an IRB submission's pre-review?
A. What are confidentiality protections?
B. Is there an appropriate risk-benefit ratio?
C. Are we protecting vulnerable populations?
D. All of the above

2. Name the item that would not be found on a template used by Duke University's IRB when a project is deemed quality improvement and not research.
A. Evidence — literature review and synthesis
B. Project aims
C. Inclusion and exclusion criteria
D. Data collection plan

3. Which of the following questions should be included on a checklist that is used to determine whether a project is human subjects research or quality improvement, according to Marilyn Hockenberry, PhD, RN, PNP, FAAN?
A. Is the activity intended to improve the delivery of care while decreasing inefficiencies within a specific health care setting?
B. Is the activity intended to evaluate current practice and/or attempt to improve it based upon existing knowledge?
C. Is there sufficient existing evidence to support implementing this activity to create practice change?
D. All of the above

4. According to Heather Cathrall, MBE, CIP, the short form consent process for non-English speaking subjects may not help expand the potential subject pool.
A. True
B. False