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Your Practical Guide To Institutional Review Board Management

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Small IRBs should add networking to their toolkit

Cost-effective knowledge

Keeping a small IRB in the know on the latest regulatory requirements, technological advances, etc., is a huge challenge. Some smaller IRBs have found that one cost-effective way to increase their knowledge of current requirements and trends is to be part of a networking group.

"We talk about the issues and concerns that are common to IRBs," says **Eric Allen**, CIP, director of research compliance at the University of North Carolina at Greensboro.

Among the common themes identified by Allen's IRB networking group are the topics of how technology is evolving, cyber security and regulatory issues, and informed consent, he says. *(See story on cyber security, p. 40.)*

"We talk about how we struggle with an issue from a compliance perspective or from an institutional support perspective and discuss how you address this," Allen says.

Small IRB offices need the support and information that is possible through networking with peers, says **Bonnie Frisard**, MBA, director of the human research protection program at Catholic Medical Center in Manchester, NH.

"There are so many organizations that participate in research and have a very small IRB office," Frisard says. "I'm a department of one."

Directors of small IRBs often have no one within their organization to turn to when there's an in-depth question or problem, she notes.

"There are several people within the organization who I can contact for assistance, including the IRB chair, IRB members, corporate compliance, and medical staff director," Frisard adds. "But for in-depth understanding or interpretations, my peers at outside organizations are most helpful."

Small IRBs are different from an IRB at an academic hospital, as many smaller IRBs do not deal with phase I or phase II studies, she says.

Another benefit of a networking group is that it fills in educational needs and gaps, Frisard and other IRB managers say.

"Part of the problem is, a small research institution has a very limited budget so education is hard to come by other than online opportunities," says **Erica Tauriello**, CIP, manager, human research program at Wentworth-Douglass Hospital in Dover, NH.

Tauriello is part of the mentoring group that Frisard started in 2011. Six New Hampshire human research protection managers or IRB directors meet each quarter to share ideas, concerns, and knowledge.

"We've helped each other understand a change in regulations for IRBs or a change in regulations for clinical research," Tauriello says. "Some of us have draft standard operating procedures [SOPs] and have developed SOPs, and we were sharing ideas."

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Editorial Questions

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The networking group also shared their strategies on specific topics such as informed consent, she notes.

While any IRB director might find some IRB tools and information online, these general templates might not be a perfect fit for smaller research institutions, she adds.

"It's easier when you're sitting with a group of people from similar institutions, looking at each other's procedures to see what's working and helping each other with it," Tauriello explains.

The local IRB networking group operates a little like the online IRB Forum, providing information and support, she adds.

In North Carolina, a grant helped fund a networking consortium that lasted a few years, Allen says.

"When it died off, it gave us contact information so we could form our own little network," he says. "I'm on a local IRB here and they've started another small consortium and have included me in their network."

The new networking group has 16 to 20 people who aim to meet quarterly, he adds.

Face-to-face networking groups have more confidentiality and greater flexibility, Allen and Frisard say.

"You can ask questions on the IRB Forum, which is wonderful, but there might not be an immediate response for follow-up," Frisard explains.

Sometimes a person who would like to see templates for certain forms will ask people to send them samples to their private email accounts, which means the other people on the forum do not get to see the information, she adds.

For directors of small IRBs, the networking group also can improve morale, the experts note.

For instance, in New Hampshire many hospitals were hit hard with budget cuts in recent years. Hospitals responded by reducing or eliminating travel to conferences and professional educational opportunities, Frisard says.

"So most of us didn't get to go to the PRIM&R meeting, which is where you see your peers and hear about what they're doing," Frisard says. "Meetings are where you see that you're not alone in the world."

The networking meetings, held at each participant's organization, are relatively inexpensive while still providing the social and professional reward of a face-to-face meeting or session, she adds.

The main benefit of networking is to help IRB directors find different ways of looking at problems and addressing regulatory and other issues, Allen says.

"Once you've been in the human subjects protection business for a while you know the rules, but this helps you look at them from different perspectives and explain them to different groups," he says.

"Overall, the networking group is one of the most beneficial things you can do," Allen says. "You are part of a group that brings you information so you don't have to seek it out."

Networking meetings spark discussions and allow people to work on possible ways to resolve issues that arise, he adds.

It also gives IRB directors who work solo another person with whom to discuss their issues and ideas.

"When we are having a problem or issue or are trying to develop something new, we have somewhere to turn," Tauriello says. "We have somebody to ask a question and bounce off our ideas."

Tauriello works alone in her IRB office. Her only peers are the IRB chair, IRB members, and clinical research personnel.

"We talk things through, but nobody else covers the IRB end of it except me, and this is true of most of the people in this IRB network," she explains.

"We send each other emails or call each other and say, 'Hey, can you help me?'" she adds. "We're glad to have the network where we can get help from each other." ■

Quick tips on starting your own IRB network

First step: find peers

IRB directors seeking to start their own local IRB network can make this happen with just a little up-front effort, experts say.

They should simplify their networking plan by seeking out IRBs of similar sizes, suggests **Erica Tauriello**, CIP, manager, human research program at Wentworth-Douglass Hospital in Dover, NH.

"I don't typically contact people from larger institutions because small institutions have specific issues and limited resources, and that drives what you can and cannot get done and what you can expect to get done," she adds.

IRB directors also should decide what types of IRB offices would fit in their network. For instance, IRB directors might gain the most from a network where other members have similar types of research and institutional pressures, says **Eric Allen**, CIP, director of research compliance at the University of North Carolina Greensboro.

One good strategy is to keep the networking group fairly small with meetings on a schedule that works well for busy IRB directors. For instance, an IRB network in New Hampshire meets once a quarter, says **Bonnie Frisard**, MBA, director of the human research protection program at Catholic Medical Center in Manchester, NH.

Here are some other networking suggestions by Tauriello, Allen, and Frisard:

• **Find other networkers:** Frisard decided to start a network in New Hampshire and spent some time looking for other small IRB offices. She began by looking at a list of organizations that held Federalwide Assurances (FWA) in New Hampshire, and she looked at a list of research organizations that had received accreditation from the Association for the Accreditation of Human Research Protection Programs (AAHRPP) of Washington, DC.

Then Frisard called the organizations on her list and tried to find the person in charge of the IRB or human subjects protection office.

"It took a couple of tries to identify who the people were," she recalls. "When you call hospitals, especially if they're small community hospitals, they might not know what the IRB is."

• **Share sources, tools:** Network members can bring their resource information and tools to these networking meetings to share with other members of the group. For instance, network members can discuss their privacy rule strategies, sharing information that each member can use and take back to his or her own institution, Allen says.

Also, members could share online resources — including articles and journals — as well as policies and procedures and IRB forms, Frisard says.

"Our goal is to discuss current practices and share information to improve our human research program," she adds. "We've brought our periodicals like *IRB Advisor* to the meetings."

Members honor copyright laws, but sometimes share resources at meetings, she says.

At one meeting, members shared their flow charts for serious adverse events, she says.

Someone might find a chart that is an improvement over their own. Then they could take the sample, modify it and fit it to their own needs, Frisard explains.

The networking group can share strategies and tools that they might be unwilling to make public online, Tauriello suggests.

"Not everyone has their standard operating

procedures (SOPs) on every topic available online," she adds. "If you're trying to tackle an issue and see how it will apply at a small research institution, then this could be discussed in a networking group."

• **Set agenda, meeting schedule:** The New Hampshire IRB networking group has a fairly casual organizational structure with participants meeting each quarter. Each member volunteers to host a meeting, and the host is the person who will send out email reminders, Frisard says.

At the first meeting, networking members introduced themselves and discussed their hospital, including how many studies they do and whether they have a specific research focus, Frisard says.

Networking meetings can have a single topic focus, such as education for IRB members, she notes.

The key to keeping a networking group active is to select a meeting agenda that works well with members' schedules, Tauriello notes.

"Our group will continue to meet, and it may expand, but some people haven't come to meetings because their schedules won't allow it," she says. ■

Cyber security will be this decade's key issue

Who is responsible party?

Cybercrime and data exposure pose a relatively new risk to research participants. IRBs have been addressing this threat in recent years, but they haven't given as much thought to their own responsibility and risk from wireless technology, an expert says.

"Sixty-five percent of people who use information online will have a cyber-attack in their lifetime," says **Eric Allen**, CIP, director of research compliance at the University of North Carolina Greensboro.

"It's easier to target data floating around on the Internet," he says. "Even when something is considered anonymous, there are small risks that will build up for individuals over time."

IRB offices need to be aware that any electronic exchange of data poses security risks. While all research institutions install firewalls in their electronic systems, these are not airtight, particularly if they are not regularly updated, he notes.

"If you are sharing data online, are you informing the people you communicate with that you are working in a virtual environment and they need to be sensitive to privacy and confidentiality?" Allen says.

Also, IRBs should be concerned about what happens with data after it's archived and inactive.

"How long do you keep it? How long do people have access to your data?" Allen asks. "When they leave, do they take the data with them?"

In this era of instant connectivity to large communities and populations, IRBs and research institutions also face immediate and widespread risk and exposure from mistakes.

"If you make an ethical mistake in research now, it is no longer confined to a few people in the neighborhood," Allen says. "You could have the whole state, the whole nation knowing what happened in a few minutes."

IRBs sometimes find that middle-aged researchers are unaware of the potential harm of some of their online activities. For instance, there was a situation where a researcher wanted to post pictures of participants who were minors on a Facebook page, Allen explains.

The researcher didn't consider the consequences, such as cyber bullying, he adds.

Although the photos were going to be listed anonymously and in a positive context, this exposure posed much greater risk in the Internet environment than it would have on a paper brochure.

"They thought they could post these pictures on Facebook and no one would know who they were," Allen says. "They had done this with brochures, but when you do this in a virtual realm it's different."

IRBs need to stay aware of these types of risks and educate investigators about them.

Allen often speaks with other IRB and research leaders at conferences about cyber age risks in research.

"When many of the research rules were written in the 1980s, cybercrime wasn't a big deal," he says.

In this decade, cybercrime has become a big business with organized crime and professional hackers involved, he adds.

"There are people who are paid $30,000 a month to hack into a particular large organization," he says. "The bigger the unit the more credibility they get and the more products — like worms and viruses — they can sell."

Research institutions are not immune to this mischief. In one recent case, a research institution had a large database without updated security measures. The university said it was the investigator's responsibility to make the data fully secure. The investigator countered that it was the university's responsibility, Allen recalls.

When a breach happened and a hacker obtained a few hundred thousand Social Security numbers, exposing breast cancer research study participants to

risk, the university had to spend a lot of money on informing people of the breach, he adds.

IRBs can help reduce this risk by asking investigators for details about their data security measures. Allen suggests they start with these questions:

• What kind of data do you need to do the project — not just what is convenient, but what do you really need?

• How long do you need to keep data for the study's analysis? Think more in terms of weeks and months rather than years.

• How will you transfer data? "Don't just e-mail it; that's not the most secure way to send information," Allen says.

• Have you scheduled audits to make sure information is secure and that your security measures meet current standards?

• Will you update your security measures regularly?

• Are you taking simple security steps, such as turning off your computer when it's not in use?

"The cybercrime technology grows faster than the technology we use to catch it, so you have to make your computer not as accessible and develop a long and complicated password," Allen says. ■

Expert: Develop process to assess needs

Performance metrics help

Human research office managers sometimes need to identify ways to improve workflow and efficiency. One way to do this is to develop a process for evaluating resources and assessing needs, an expert advises.

A research department that oversees various regulatory offices has to weigh competing needs with limited resources, notes **David Wynes**, PhD, vice president for research administration at Emory University in Atlanta.

"We all have limited resources, so the key thing I have to rely on is a timely program evaluation," he says.

Any human research protection program (HRPP) or IRB office that has not done a clear program assessment probably doesn't know what kind of resources and opportunities are available, he adds.

"You need to know where you have weaknesses and where your needs are," Wynes says.

Program assessments should be a regular occurrence since regulatory and institutional changes make it counterproductive to maintain the status quo, he adds.

For instance, with the advanced notice for proposed rulemaking involving the Common Rule, now is a good time to perform a program assessment.

Wynes offers these suggestions for how to perform a program assessment:

• **Identify goals:** "What is it in theory that you're trying to accomplish?" Wynes says. "How is the program supposed to operate?"

Other questions to ask are as follows:

— Does your goal include achieving compliance with the Common Rule, Food and Drug Administration (FDA), or Association for the Accreditation of Human Research Protection Programs (AAHRPP) of Washington, DC?

— Do you include in your goal statement the purpose of protecting research subjects?

— What are the activities your program does that go beyond its goals and mission?

— Have you identified IRB mission drift?

"You look at it and say, 'Are we doing what we set out to do or are we doing more?'" Wynes says. "If you are doing more, then you need to ask if that's intentional or accidental."

• **Look for dynamic situations:** "There are dynamic situations where maybe the theory you started with is no longer there," Wynes says.

For example, the regulations do not require human research protection programs to have a post-approval monitoring program, he says.

"I would maintain that if you don't have a team to conduct post-approval monitoring, then you don't know what's happening in the field," Wynes says. "If you rely strictly on the paper or electronic reports that come in from the field, you won't have a true picture of what's happening at your institution."

So in situations like this, a program might go beyond its original mission, but this extra work serves the overall purpose, he adds.

In another situation, an IRB might have a rule to never provide expedited review for studies. Every protocol submission receives full board review.

"In those cases, I would hope they'd look at it and say, 'Why do we do things that way?'" Wynes says. "Maybe they have a reason, but larger institutions might crumble under the weight of that process."

The program evaluation should include a look at the theory behind the rule and its implementation. Then the HRPP manager should assess the impact and effectiveness of continuing

the current practice, he adds.

• **Design performance metrics:** With metrics, an HRPP director could quickly spot problem areas.

"Are we doing the turnaround on an expedited review that we should be doing? Are we doing turnaround on a full-board review?" Wynes says. "You have to have metrics and customer feedback on what is working or not working in the process."

The metrics could include FDA inspections, sponsored audits of investigational new drug trials, and other data that already have been collected.

Also, the metrics should include efficiency and workflow measures.

"We all know there are multiple ways of doing things, so look at the workflow," Wynes says.

One suggestion for assessing workflow is to have managers develop process maps, he suggests.

"This past fall I brought in someone to conduct a workshop on process mapping for my senior leadership," Wynes says. "I asked all of them to do process mapping, and then we'll look at those maps as we go along."

The purpose of a process map is to outline what employees are doing and why they are doing it.

"Then you challenge and question it and look for critical information that gets you to the point where you need to be," Wynes says. "If we go through process mapping, and I find I have a resource problem, then that puts me in a better position to find solutions."

For instance, Wynes can use the process mapping findings to make a better case for hiring new staff or to shift resources from a less critical area to an emerging need.

"Look at what metrics are available, and there should be many as we move to electronic systems," he says. "There are metrics embedded in databases that most people might not think about."

• **Use data to provide staff feedback:** The goal is to find information that could lead to small operational changes and efficiencies, Wynes says.

"What your program theory says doesn't synch with what people are doing because there will be mission drift over time, and people have competing demands," he says.

"I've done things like asked people to say during annual reports what their goals are for the coming year," he explains. "Then we talk with their directors about their goals and how these fit with the institution's mission."

Six months later, directors could come back with reports on how the employees did in meeting those goals and provide feedback.

"Ask for their goals once a year and check on them against the previous year," Wynes says. "I want this to be intentional; if something changed, that reason should be articulated." ■

IRB agreement used for multisite studies

IRBs can cede review if needed

Multisite studies are a continuing challenge for IRBs — how do you review these protocols quickly and efficiently while preserving the autonomy of individual IRBs?

In Boston, a group of nine collaborating institutions has developed a solution that addresses both those concerns.

The institutions are all affiliated with the Harvard Catalyst, a clinical and translational science center based at Harvard University. They have been working together for three years under a reciprocal IRB reliance agreement, which allows them to cede review of a multi-site protocol to a single IRB.

The agreement was worked out over the course of a year, by about 100 representatives from all of the institutions, in order to craft a process that could be used with a variety of protocols, says **Barbara Bierer**, MD, senior vice president for research at the Brigham and Women's Hospital as well as the director of the regulatory knowledge and support program for the Catalyst.

"We had all the major players — the vice presidents for research, the office of general counsel and the IRB chairs — working together on this," Bierer says. "These people sat in a room for a year and really came together to understand the reliance agreement and all of its issues."

Bierer says that prior to this arrangement, when investigators from these institutions worked together on projects, they had to seek either separate reviews from all of the institutions involved or a one-to-one reliance agreement for that specific protocol.

"Often, our investigators were taking one protocol and submitting it to three or four IRBs for review and sometimes re-review," she says.

So when the institutions came together to form the Harvard Catalyst under an NIH Clinical and Translational Science Award, one of the first areas they looked at was streamlining this process.

"We focused on decreasing the administrative burden, increasing inter-institutional collaboration and trying to engage the institutions in a process that

would simplify investigator collaboration," Bierer says. "We decided to have a master agreement, so you wouldn't need individual signoffs. And that master agreement would cover all of the eventualities that we could foresee."

The reliance agreement was honored recently by the Health Improvement Institute with its Award for Excellence in Human Subjects Protection – Best Practice.

Voluntary decision

Under the agreement, ceding review to another institution's IRB is entirely voluntary for each study and each participating institution. The decision by an institution to handle review for the group or to cede review is made before the investigator officially makes an IRB submission, based on information that he or she provides to the group about the study. Once that decision is made, however, an institution cannot change its mind and demand a separate review.

"Once they decide to rely, they can't read the review of the IRB, and say, 'Now I don't want to rely anymore,'" Bierer says. "You do have to actually rely on somebody, and if there's an issue, you have the ability to go to the IRB and work with that IRB, but you can't strip the IRB of its autonomy."

An investigator who wishes to use the ceded review system is generally required to use the IRB at the institution where he or she is employed, in an effort to avoid "IRB shopping," Bierer says. However, that IRB may make a decision on its own to cede review to another IRB that has particular expertise with a subject.

"This other IRB may be set up specifically for pediatrics, for example, or prisoner research or international research," she says. "So the IRB will cede to it, even though the PI is at their own institution."

The submission is made through a separate electronic system than the Catalyst members' own IRB systems, using a special ceded review request form. This allows the same information to be sent to all of the participating institutions, and for each institution to track its progress.

"As far as Barbara and I know, the ceded review form is the first common form that all the Harvard IRBs have ever accepted," says **Sabune Winkler**, JD, director of regulatory affairs operations for the Catalyst. "It is standalone and it's designed that way."

Each institution looks at the information about the study and decides whether to cede review to the IRB handling that study. How that decision gets made, and by whom, can vary from site to site or even from study to study, according to Bierer and Winkler.

Winkler says that when an IRB chooses to review the protocol for the group, the principal investigator submits to that institution, using all of its forms and policies.

Hundreds of multisite protocols have been handled through the ceded review process, Bierer says.

Winkler notes that this process is used for all kinds of protocols, not just simple, minimal-risk studies.

"When we talk to people, they're really surprised that we didn't limit it to minimal-risk studies," she says.

Spreading the word

Other institutions have shown interest in adopting a similar model to the Catalyst's reliance agreement. Bierer and Winkler say they've worked with 20 to 30 institutions, explaining how they developed their agreement and the challenges they've overcome.

"We give them the template, and we do tell them a few things," Bierer says. "One is to get the right people in the room [working out the agreement] and to not expect this to be a slam dunk."

Because the Catalyst group has had several years to work with the agreement, Winkler says it has hammered out a lot of the practical details that other institutions may not have identified yet.

"Whether you want common subject injury language, for example, or whether you want to have the right to have another institution go in and audit you," she says. "We realize when we're talking with other institutions that they had really not gotten that far; they were just looking at a document." ■

Ceded review streamlines study approval

Agreement adds to workload but helps IRBs

IRB administrators who use the Harvard Catalyst's ceded review system say it performs as promised — providing a more efficient way for institutions that collaborate frequently to handle multisite studies.

They particularly praise the voluntary nature of the process — an individual institution can choose to cede review to another IRB or not for every protocol — as key to its success.

"What has worked well here is just the philosophy that we can choose to accept or deny a reliance agreement," says **Susan Kornetsky**, MPH, director of clinical research compliance at Children's Hospital in Boston. "In the end, we have ability to decide if we want to rely or not."

Kornetsky and **Leigh Read**, CIP, senior research programs administrator at the Joslin Diabetes Center in Boston, serve as gatekeepers for the ceded review requests that come to their respective institutions.

Kornetsky says she receives roughly three to five such requests a month; Read sees them less frequently, about once or twice each quarter.

Both say the requests they often receive are for minimal risk studies — perhaps involving transfers of data or recruiting subjects at one institution for a study being conducted at another.

In those cases, Read and Kornetsky say, they often make the decision of whether to cede themselves.

"It really depends on the type of patient contact," Read says. "If it's a complex study, and patients are being seen here, I may go to my [IRB] chair and to my institutional official and say, 'I've reviewed this, this is what's being done, I recommend we cede or I recommend we do not cede,' and they would make the final decision."

For one study, Kornetsky says, the decision of whether to cede review was actually referred to the IRB itself, because of the intricacies of the study. The board reviewed the proposal and decided to allow the ceded review, but to keep an eye on some aspects of the study internally.

"It was in a very unusual situation, but it worked well," she says.

Administrator burden

Barbara Bierer, MD, director of the regulatory knowledge and support program for the Catalyst, notes that because the IRB administrators must look at all of these ceded review requests to determine how to handle them, it does increase the burden on those administrators.

"One thing we didn't appreciate at first was the fact that you need somebody to take this on as part of their job," Bierer says. "On the other hand, for our IRBs, it's really been an improvement. For the system, it decreases work."

Kornetsky and Read confirm that they've contended with this issue in their own operations. They say the requests from investigators are not always complete or filled out correctly, and they sometimes must take time to track down details about the study before making a decision about how to handle a request.

Turn-around time is also a consideration, Read says.

"When I do get a request in for a ceded review, the investigator usually wants an answer as fast as possible," she says. "So if all of the information is not in the report and we need to ask the investigator questions, and go to the other IRB administrator and say, 'What do you think?' … for me, it does add some extra work. Sometimes I'll have to take the everyday stuff that I've been doing and put it to the side to address [the ceded review request]."

But both she and Kornetsky also agree that the Catalyst's reciprocal reliance agreement has improved efficiency overall in their IRB offices.

"If anything, it's increased my workload, but it certainly has decreased the IRB's workload, and that of the other administrators," Kornetsky says.

Read says the process has benefited investigators at Joslin, who often collaborate with colleagues at other institutions. Joslin is a specialized diabetes clinic; it may lack some equipment necessary for a particular study, so its investigators collaborate with someone at a larger hospital.

"For example, we do some studies here that involve an MRI procedure," Read says. "The only procedure that's going to be done at the larger hospital is the MRI. The majority of the time, the larger hospital will cede review to us for that."

Prior to the reciprocal agreement, she says, the investigator would have to submit the protocol to Joslin and the other hospital for review.

"Both IRBs would review it — we would probably recommend changes, they would probably recommend changes," Read says. "They'd have to submit their changes to us, and we'd have to submit our changes to them.

"It really did make the process of collaboration difficult."

Comfort level

Read and Kornetsky say that since the agreement has been in place, IRBs at all of the institutions have become more comfortable ceding to one another.

"I think in the beginning, people, including ourselves, would not think about this for an interventional trial, some type of drug trial, something done in the hospital," Kornetsky says. "I think people are getting a little more comfortable but are still very careful in deciding when it makes sense [to cede] and when they would rather review it."

She sees this type of arrangement as a good one for any institutions that collaborate frequently.

"If you know you're going to work together a lot and there's a lot of cross-institutional research with the same people, this works well, because you don't have to do an actual reliance form every time," Kornetsky says."

She says the Harvard Catalyst and other partnerships formed around the NIH's Clinical and Translational Science Awards (CTSA) are a natural place for these reciprocal agreements to start.

"Just by the nature of being organized in a CTSA agreement, you're going to be reviewing with the same people frequently," Kornetsky says. "So this would be a perfect solution."

Read says that organizations seeking to create a similar agreement need to make sure all of the pertinent details are nailed down before the process is in use.

"Make sure that you look at everything that may happen and get it into the agreement up front," she says. "Think about what this agreement is for, what it's going to do, and get everything in there, so that it's usable for your investigators, it's clear."

She says it's also important that all of the participating institutions feel that they've had input into the agreement. A process that seems to be driven by the needs of one particular institution won't be as successful.

"When the Catalyst did it, there was really no one institution, that took the lead," Read says. "Yes, there were times when one institution said, 'I want this in it,' but the right people talked it out and got to a point where everyone was comfortable.

"It really has to be a collaborative effort." ■

Guiding researchers every step of the way

Education program vital to QI

At Cedars-Sinai Medical Center, research compliance depends on a continuous loop of quality improvement and education, each enhancing the other.

And that loop starts early — often before an investigator even begins work at Cedars-Sinai, says **Eifaang Li**, DVM, MPH, CIP, director of the office of research compliance and quality improvement for the Los Angeles-based institution.

"Whenever they recruit a new researcher, we receive a notification of where they're coming from and what their start date might be," Li says. "We reach out to those new investigators while they're still at their previous institutions, introduce ourselves to them and recommend that they contact us and work with us for the submission of their first IRB applications, because we have online submissions.

"We have many investigators who actually submitted their first IRB application to Cedars-Sinai while they were still at their previous institutions."

The education and quality improvement program has evolved over the past decade to support investigators and research staff from that very early point, through their first submissions, into post-approval and beyond, says **Rebecca Flores**, CIP, manager of operations and education.

"We work in close partnership with our quality improvement program," Flores says. "Quality improvement helps to develop surveys and obtain feedback from the research community. We do post-approval audits, we do audits of the work done by our analyst team that processes submissions and we find trends and areas for improvement and then structure educational programs based on that."

Cedars-Sinai's education initiatives were recognized by the Health Improvement Institute as a best practice in HII's 2011 Awards for Excellence in Human Subjects Protection.

Redesigned program

Flores says Li completely redesigned the research compliance program when she arrived at Cedars in 2000, establishing the education component.

Over the past decade, it has grown to include different elements:

• **Grand Rounds**: The IRB holds quarterly presentations, bringing in nationally recognized speakers to talk about topics pertinent to the research done at the institution.

"We try to bring in speakers who bring a unique perspective and that are in alignment with our philosophy as a research institute," Flores says.

• **Continuing education**: Like other institutions, Cedars-Sinai has required education in human subjects protection for investigators, incorporating the online CITI course. When that program is completed, the investigator must continue to update his or her education by attending IRB Grand Rounds or by taking online courses developed at Cedars-Sinai.

"In those online modules, we focus on particular topics that have come up in our interactions with research teams, information we pick up as part of our post-approval monitoring program or the feedback we receive from surveys we put out,"

Flores says.

A researcher must earn four of these IRB credits within four years in order to be renewed to conduct further research, she says.

Research support staff must complete a course called IRB 101 within six months of hire as part of their initial orientation. The course introduces staff to concepts related to the ethical conduct of research, going into detail about issues such as the consent process.

• **Mandatory pre-review:** Any investigator who submits a study undergoes a pre-review by an assigned analyst, who looks at all of the documentation with a focus on meeting the regulations.

"They're looking at whether there is enough information in that submission for the IRB to make the required determination for approval," Flores says. "They work with that study team to make edits and to get it to the point where hopefully, if it goes to committee, it can be approved with very minor changes or no changes at all."

Flores says that since the pre-review was implemented in 2007, the number of IRB submissions that have obtained straight approvals has increased.

After approval

The office continues to seek information past the point of IRB approval, through post-approval audits and by studying the metrics it collects about the time taken to process submissions, Flores says.

"We have an online system that has a robust auditing and tracking mechanism, so our quality improvement team gives us very detailed and robust data," she says. "We could say, 'Wow, we're spending a lot of time on pre-review. Why are we spending so much time?' We're able to critique where we're holding things up and try to problem-solve around that."

The office can audit requests for changes made by IRB staff, to make sure that the changes are needed.

"So we're constantly looking at what we're communicating and making sure it's on the mark and not going beyond where we want to be and unnecessarily delaying the submission," Flores says.

The compliance office also surveys investigators immediately after they've received IRB approval, which can often lead to useful feedback that helps the office make changes, Li says.

For example, Cedars-Sinai's online IRB application form prompts investigators to fill in certain categories based on the type of research involved. An investigator working on a compassionate use protocol noted that the form didn't address that situation's special circumstances, Flores says.

"They were directed to all questions related to clinical trials, which for a compassionate use protocol, are difficult, if not impossible to answer," she says.

Now, she says, the online form automatically directs an investigator working on a compassionate use protocol to the questions directly related to that type of activity.

Feedback on the survey also led the compliance office to institute "IRB live chat," a 9 a.m. to 5 p.m. service each weekday that allows investigators to talk to IRB professionals to ask specific questions about their submissions.

Flores says the idea was proposed by a senior staff member. She says IRB staff have opportunities for advancement based on coming up with new ideas to help the office in its educational goals.

"They come in as entry-level analysts and if they're interested in promotion, they can go up two to three steps from that entry level," she says. "Part of their promotion involves creating an educational initiative or an operational initiative to help address a need. It really helps with staff retention. We want to give staff leadership opportunities. Even though we don't have 10 managers in our office, our staff can gain some of the skills they could be developing as a supervisor or manager."

Flores says one key to the success of the Cedars-Sinai education program is that it is seen as an integrated part of the research compliance function.

"I think if you can become comfortable with the idea that education actually enhances your ability to run a compliant program, you'll see that it's not so much an extra investment but something that's critical to your success." ■

IRB focuses on children, pregnant women

Decision to divide based on increasing research

When an institution's study portfolio gets large enough, its IRB must decide: Is it time for a new board? And if so, how do you divide the work? At many institutions, that division is based on methodology — studies are assigned to either a biomedical IRB or one devoted to social-behavioral

studies.

At Orlando Health Inc. in Florida, IRB officials looked to the growing number of studies being generated by two of its affiliated hospitals — the Arnold Palmer Hospital for Children and the newly opened Winnie Palmer Medical Center for Women and Babies — and created a dedicated IRB for research involving children, infants and pregnant women.

IRB Manager **Jonathan Lin**, MHSE, CCRP, says the idea was to provide more comprehensive review of these studies by bringing to the board members with different pediatric specialties.

"We thought there needed to be more of a precise review from different types of expertise among the pediatric realm," Lin says. He discussed the development of this new IRB at PRIM&R's recent Advancing Ethical Research Conference.

New specialists

Lin says that on the original Orlando Health IRB, members included an obstetrician-gynecologist and a pediatric cardiologist, because the Arnold Palmer Hospital has a strong pediatric cardiac care program.

The newly-formed Arnold Palmer Medical Center (APMC) IRB has added more specialists, including second OB-GYN, a neonatologist, a pediatric pharmacy specialist and a pediatric emergency physician.

"They're all bringing in their backgrounds and providing their perspectives within the review," Lin says. He says the members all have extensive research experience and previous IRB experience.

Adult research is now handled by the original IRB, renamed the Orlando Regional Medical Center IRB.

In creating the new IRB, Lin says he looked to existing IRBs at children's hospitals.

"I consulted with a few IRB managers or IRB representatives from those institutions," he says. "They definitely provided a lot of guidance. They directed me to their policies and procedures, and I'd see how those matched up with our state law and our institutional policies."

He says the process required creating new forms for the new IRB, including an assent form for pediatric research written in appropriate language for children.

But the biggest change was in the way studies are reviewed, Lin says.

"We provide consistent review between both IRBs, but the new IRB is very specific in addressing and documenting the reviewers' determinations with regards to the subject population," he says. "There's a lot more discussion on the APMC IRB than when the IRBs were [combined], because people are bringing their backgrounds to the table and bringing different concerns that were not previously missed, but maybe not emphasized in these [combined] IRB meetings."

He says the research conducted with pregnant women hasn't raised many new issues because it tends to consist of minimal risk studies, such as surveys and chart reviews.

Balancing workload

When the APMC IRB was created in September 2010, 98 studies out of the existing load of 350 were transferred to it. Currently, Lin says, there are still more adult studies being handled than pediatric

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

- HRPPs can assist in educating research staff
- Dementia and surrogate consent a complex issue
- Coming to consensus on incidental findings in genetic research
- Check out these cool tools

and pregnant women studies, but the workload is balancing out more.

Operationally, the addition of a new IRB has helped the office run smoothly, he says.

"We've tried to have the turn-around remain the same or even shorter," Lin says, noting that he can move IRB members from one board to another in to help maintain a quorum if a member can't attend.

An institution considering creating a new board should focus on two key factors, he says:

— **Choosing members:** The roster should well represent the various specialties the IRB commonly will be encountering in review.

— **Creating forms:** This can be time-consuming, Lin says, but is important, as the forms must document all of the additional safeguards and regulatory requirements involved in research with vulnerable populations. "I saw it as a way of investing up front rather than having to change forms later," he says. "If we create forms and then change them constantly, we lose trust." ■

CNE/CME QUESTIONS

1. Which of the following is a potential benefit of IRB networking?
   A. Sharing tools, templates, and information
   B. Providing a morale boost with face-to-face peer support
   C. It's more cost-efficient than conferences and training sessions
   D. All of the above

2. Which of the following is one of the more cost-effective and simplest ways for research institutions to make electronic data more secure?
   A. Schedule regular audits of data security measures
   B. Update cyber security software regularly
   C. Turn off computer when it's not in use
   D. Back up everything with hard files

3. True or False: In the Harvard Catalyst's ceded review system, an IRB that has ceded review of a multisite study to another institution can change its mind and review the study separately if it is unsatisfied with the other IRB's decision.
   A. True
   B. False

4. Which of the following has not been an effect of the Catalyst's IRB reliance agreement?
   A. Researchers have an easier time getting approval for multisite studies
   B. IRB administrators' workloads have lessened
   C. IRB office efficiency has improved
   D. Inter-institutional communication has improved