IRB ADVISOR

Your Practical Guide To Institutional Review Board Management

AHC Media LLC

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Challenging conventional wisdom that IRBs delay clinical trials

Still, steps to improve can be taken

The conventional wisdom in research circles is that IRBs are the main drag on the process, slowing down the progress of a clinical trial with an unnecessarily complicated review system.

That's what **David Dilts**, PhD, heard too as he started to examine the process for activating clinical oncology trials. Dilts is director of the Center for Management Research in Healthcare at Vanderbilt University in Nashville, TN. He has studied operations processes in various other industries in addition to healthcare.

Dilts and his team minutely examined all the processes involved in activating a clinical oncology trial to see what slowed things down, using the Vanderbilt-Ingram Cancer Center (VICC) and its affiliate network as an example. His goal was to find the points in the process where the most delays occurred so that trials could be opened faster.

"Before I started the entire process, I had absolutely no preconceived ideas as to what it would be and almost universally, everybody told me it was the IRB," he says. "What we found out was more often than not, it was the contracts — that contracting was a major holdup."

In fact, his data showed that the IRB process was actually faster than both the contracting and scientific review processes at VICC.

Dilts says IRBs aren't completely off the hook — he faults them for failing to gather hard data on their own operations in order to identify ways in which they could improve. And he believes that solutions currently under discussion, such as alternative models of IRB review, could help the situation.

"But if you're in an organization that thinks if we cut our IRB time in half we're going to open studies twice as fast, the answer is no," he says. "That doesn't absolve IRBs from making the processes better. But to blame the IRBs — we have not found that to be the main factor."

Dilts and his colleagues first detailed all the steps for opening a trial at VICC, using a team of experts from the cancer center, the Vanderbilt School of Engineering and the university's Owen Graduate School of Management. In total, they found more than 110 steps involved in acti-

vating a study. Then they looked at how many of those steps actually added value, and found that only 50% of them overall did so. Of the steps involved in the IRB process, less than a third were considered value added.

Dilts gives an example of what might be considered a non-value added IRB step, noting that at one organization, staff might spend a day making 25 copies of every protocol, stacking them and sorting them into envelopes, which then would get delivered to each IRB member.

"The question is how did that increase the safety of the study? How did that do anything in with regard to the efficacy of the process?" Dilts says. "It didn't. That was pure busy work. If you scanned them into a PDF, sent them out in one email, everybody's got it and you've saved yourself an enormous amount of time and effort. That's a classic non-value added activity that you can easily get rid of."

Dilts' team looked at more than 200 protocols handled by VICC and its affiliate network from January 2001 to June 2005, using archival timing data to determine how long each process took.

They found that the median time to open a trial at VICC was 171 days. The median time for the IRB process was 47 days, compared to 70 days for scientific review and 78.5 days for contracts.

Dilts and his colleagues also have studied NCI-funded cancer cooperative groups. In one case, the Cancer and Leukemia Group B, the process itself was much more complex, with more than 300 steps, and took much longer. But again, the IRB process itself (this time handled through the NCI's Central IRB) was among the fastest.

Why then do IRBs so often get blamed for slowing things down? Dilts thinks it may be because IRB delays are much more apparent to investigators than contracting problems.

"Investigators have to actually do something when the IRB makes comments," he says. "But investigators don't have to do anything when the contract is being negotiated, so the perception is, because I'm busy, this must be the problem."

A dissenting viewpoint

Not everyone agrees with Dilts' findings. **Norman M. Goldfarb**, CRCP, managing director of First Clinical Research of Palo Alto, CA, and editor of the Journal of Clinical Research Best Practices, says data he's seen shows that the IRB review process continues to be a major problem, particularly at local IRBs.

As an example, Goldfarb points to data from one month in 2007 reported by the clinical research organization Quintiles. It shows that for sites with a local IRB, contracts took 121 days, while the regulatory process took 157. For sites using a central IRB, contracts took 28 days, com-

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pared to 44 days for regulatory.

"So in both cases, the regulatory takes longer, and in both cases, places with local IRBs take substantially longer than places that use central IRBs," Goldfarb says. "Those numbers I would say are accurate within 20% today, for the average site."

He says it's hard to analyze data about specific processes because they're all interconnected and can affect each other.

"Let's say you're at a site and you know you're not going to have an IRB meeting for another four weeks — you just missed it," Goldfarb says. "You're not necessarily going to rush to do your contract. Similarly, if you know contracts take months to do, you're not going to rush to do the IRB review.

"There are a lot of complications in analyzing the data."

While he disagrees with Dilts' findings, Goldfarb says he's glad he's working on the problem — "because nobody else is doing it."

And he warns that this issue could become more important as the industry heads into a more stringent regulatory environment.

"That will tend to slow things down." Goldfarb says. "So the problem may be getting worse rather than better."

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Helping break the logjam: What IRBs can do

Think like a business; gather data on problems

In trying to streamline the IRB process, institutions should look to other industries as an example, says **David Dilts**, PhD, director of the Center for Management Research in Healthcare at Vanderbilt University in Nashville, TN.

Dilts, who has been studying the process of activating clinical trials, says he's struck by how little many IRBs know about their own activities — how long they generally take, why things are sent back to investigators, etc.

"IRBs will know what happened to a particular study, but not to the collection of studies," Dilts says. "For example, if I was to go into an institution and ask 'Can you tell me the number one reason why things get sent back from the IRB? Using hard data.' The answer is usually no, I can't tell you. That's phenomenal to me.

"I'm an old manufacturing person and it's like saying, I run a repair shop and 60% of all the cars that come in here have a broken fender but nobody ever asks if fenders are bad. I know what happened to a particular car, but I have no overall global picture."

IRBs often can't say for sure whether the changes requested are more scientific in nature or just to address administrative or clerical concerns, he says. IRB officials often think they know what the problems are, but lack hard data to back it up.

"I believe in evidence-based medicine," he says. "If you're the head of an IRB, collect evidence on exactly why things got sent back. Were the top five things dealing with truly scientific issues or were they dealing with administrative issues? And if you can't answer that question, how are you going to get any better?

Beware of 'scope creep'

Other ideas IRBs should consider to help smooth the path of research:

- Looking for the value added. Dilts says IRBs should scour their processes for steps that don't add value to the final study and simply waste valuable staff time. What would happen if those steps were eliminated or automated?

"There are some activities that you need to have no matter what, just because they're part of the logistics of the system," he says. "But you need to ask yourself, why exactly are we doing all this paperwork? Why do we keep doing these steps? And often the answer is either A) because we always have or B) this is a really important step because this is what I do."

- Consider the customer, in this case, the investigator. IRBs should be able to provide information that investigators can use to make their plans. Dilts notes that an IRB often can't tell an investigator how long to expect the process to take.

"If I'm doing this really straightforward placebo-controlled design, should I expect it to go through the IRB one time, two times, three times?" he says.

"It's okay to say, 'A study that includes X is going to take a long time.' What I object to is the

fact that an investigator has no way to know how long it's going to take to go through the system. If you ordered a product from a department store and they say it might be in tomorrow or it might be in three months, it all depends. How in the world do I plan for 'It depends?'?"

Another suggestion would be to have someone review the submission package ahead of time, in order to help an investigator with easily-fixed problems before the IRB sees it, says **Norman M. Goldfarb**, managing director of First Clinical Research of Palo Alto, CA, and editor of the Journal of Clinical Research Best Practices. "Don't just wait until the meeting and then say, "Your package is broken."

• Be wary of 'scope creep,' or the tendency of an IRB to delve into the science of a protocol under review rather than focusing on human subjects protection issues.

Dilts notes that IRBs do have to consider the science, because it would be unethical to sign up subjects for a study that's rooted in bad science.

"There's a fine distinction between whether it's a good study or whether it's a study you would or wouldn't do," he says. "If it's a good study, then let it go."

• Have a global perspective. Dilts and Goldfarb both say that IRBs need to consider the larger clinical trials process and try to work better within it.

For example, Dilts notes that different organizations often have different systems for tracking a study.

"How many different tracking numbers are there on this trial?" he says. "You've got a scientific review number, you have an IRB number, you have a budget number — I can understand that. But show me the central cross-listing of all those numbers."

Goldfarb says that because slowdowns in one part of the clinical trial process can affect other parts of it, all the players — the IRB, contracting, budgets — should make information available as to where a study stands, so others can catch up if they're falling behind.

Dilts says that as one part of the process may improve, bottlenecks may occur in other parts.

"If I fix the IRB problem, I might then be constrained by the grant," he says. "If I fix the grant problem, I might then be constrained by the case report forms. So what happens is as you systematically fix each of the problems, it gets better, but not by the magnitude of fixing the one problem itself."

Ultimately, the IRB needs to be part of the team, from a business standpoint, Goldfarb says.

"Obviously you have to keep yourself separate from an approvals point of view, but from a business process point of view, you need to be working together to make the whole process as efficient as possible," he says. ■

Pfizer sets standard to require IRB accreditation

Pfizer's own CR unit is accredited

A major pharmaceutical company is leading the way to making accreditation as ubiquitous among IRBs as it is among health care organizations.

Pfizer of New York, NY, now requires central IRBs reviewing Pfizer-sponsored trials to be accredited by the Association for the Accreditation of Human Research Protection Programs Inc. (AAHRPP) of Washington, DC.

Also, in April, 2009, which was the eighth anniversary of AAHRPP's founding, the Pfizer Clinical Research Units of New Haven, CT, Brussels, Belgium, and Singapore, achieved full accreditation.

"We sought AAHRPP-accreditation completely voluntarily," says **Kristen E. Neese**, director of worldwide communications for Pfizer.

"We believe it's a demonstration of our commitment to integrity in research," Neese adds.

"They're the first clinical trials sponsor to be accredited, and they're international," says **David Ward**, an AAHRPP spokesman.

For all of Pfizer's U.S.-based trials, they'll use only accredited central IRBs to review U.S. multisite research, says **Marjorie Speers**, PhD, president and chief executive officer of AAHRPP.

Pfizer's newly-accredited CR unit conducts phase I clinical trials, Speers says.

"What's important is that Pfizer is now the world's leader among sponsors, industry, and governmental sponsors of research in setting one standard for human subjects protection," Speers says. "They made the decision to use only accredited IRBs before achieving their own accreditation."

Pfizer made these moves because of the recognition that accreditation is seen as a gold standard in clinical research, Neese notes.

"We see this as the gold seal," she adds. "We

recognize those organizations that are accredited, and we wanted to be among them."

So far, Pfizer is the only CR sponsor to make this announcement, although this soon could become a trend.

"I do believe there are other sponsors who use only accredited IRBs or who take accreditation into consideration," Speers says. "That's what we hear from the central IRBs: that they feel they need to be accredited."

Requiring central IRBs to be accredited is a reasonable move since the central IRB will review multisite clinical trial protocols, she adds.

Once the central IRB approves the protocol, a site can request a revision to consent documents, but sites can't change the essence of the study, Speers says.

"When the sponsor contracts with the various research sites, those research sites can use the central IRB or use their own IRB to review the study," Speers explains. "The fact that Pfizer is using AAHRPP-accredited central IRBs means a standard has been set."

Has trend been set?

More sponsors might follow suit.

"Pfizer is a thought leader and is leading the way for others," Speers says. "I fully expect to see other sponsors require accreditation, and, secondly, if they conduct their own research internally, then they would seek accreditation."

AAHRPP, which is the sole accreditation organization for human subjects research, has accredited 175 organizations, representing about 830 research entities.

"We've accredited 12 central IRBs," Speers adds.

The organization also has accredited organizations around the globe, including a medical center in Korea, a national health care group in Singapore, and a contract research organization in Canada, she says.

Organizations seeking accreditation for the first time typically spend 12 to 18 months on the process before they receive their accreditation notice, Speers says.

"In the next five to 10 years I do think there will be an expectation, if not a requirement, that organizations are accredited in order to conduct research," Speers says. "I think as more organizations get accredited and the benefits of accreditation become apparent then sponsors — whether they're from industry or the government — will rely on accreditation as a marker of excellence." ■

Many IRBs may not know member interest conflicts

Talk to your institution first, to see how others report

A significant minority of IRBs at some of the nation's biggest medical institutions lack sufficient procedures to determine when IRB members have industry relationships that could pose a conflict in their work.

That's the assessment of researchers who surveyed IRB chairs at the United States' most research-intensive medical institutions. Their findings were published earlier this year in the journal Academic Medicine. [1]

The findings showed that a third of IRBs represented in the 2005 survey had no requirement that voting members disclose relationships with industry. A quarter of the IRBs didn't have written policies outlining what to do if a member's conflict of interest was identified.

Twenty percent of IRB chairs surveyed said they didn't feel confident that their policies and procedures ensured adequate disclosure of members' industry ties.

Previous research has shown that some IRB members have had such industry relationships — research funding, work as paid consultants or as members of advisory boards, royalty earnings, or serving as officers of companies.

Christine Vogeli, PhD, instructor of medicine at Massachusetts General Hospital and Harvard Medical School in Boston, MA, and the lead author of the study, says that while the original survey was administered in 2005, she doesn't believe the situation has changed significantly since then.

"A lot of information (about conflicts of interest) has come out in terms of institutions in general, but not specifically related to IRBs," Vogeli says. "Although institutions may have set up practices to be able to record member relationships, it's not clear that those extend to the IRBs."

She says she was surprised at the results, given that federal guidance and professional associations strongly recommend that IRBs develop such policies and procedures.

"These are some of the top institutions, the ones that really bring in most of the money and

do most of the research within this country," Vogeli says. "So I guess I would have hoped that there would have been a little bit more consistency in application of the guidance."

Anonymous survey

A total of 107 active IRB chairs responded to a mailing to IRBs at the 100 medical schools and 15 independent hospitals that received the most funding from the National Institutes of Health in 2003. They replied anonymously to a series of questions about the processes in place at their institutions to manage member relationships with industry.

Of that group, 70 (or 66%) reported that voting members were required to disclose such relationships, and 25 (23.6%) required non-voting members to do so. A total of 79 chairs (74.5%) reported that their IRBs had a defined process for disclosing members' industry relationships.

There was wide variance in how members reported relationships — some reported to the chair, some to the entire IRB and others to another group or individual outside the IRB, such as a conflict of interest committee or a senior administration official.

Similarly, of the IRB chairs who identified a conflict of interest arising in the previous year, 31% said that the decision about how to handle it was made by the entire IRB, 27% reported the IRB chair made the decision, 16% said it was left to a group outside the IRB and 13% said the individual IRB member affected made the decision.

Comparisons of this survey of IRB chairs to a companion survey conducted of IRB members from the same group of institutions turned up a significant discrepancy. All 47 chairs (100%) who had reported a conflict of interest in the prior year said their members never voted on protocols on which they had a conflict. However, in the companion survey, only 64.5% of members with a conflict said they never voted on the protocols in question — 19.4% said they always voted on protocols on which they had a conflict of interest.

While the anonymity of both surveys made it impossible to know which members' responses might match up with which chairs' results, Vogeli says the point is still telling.

"I think the IRBs think they know about the relationships with their members and the conflicts that they have, but they really don't," she says. "It shows there's definitely a gap. A third of members reported that they had at some point voted on a protocol in which they had a conflict, while the IRB chairs thought that no one had. That's problematic."

Even some of the IRB chairs surveyed showed concern over the issue. Twenty% of them reported that they were "not very confident" or "not at all confident" that their procedures were providing the appropriate level of disclosure for member-industry relationships.

Looking to the institution

While Vogeli says it's important that IRBs develop policies for recording and responding to members' potential conflicts of interest, she doesn't think the answer is for the IRB to simply come up with its own plan.

Instead, she says, the first step should be for the IRB to look to its institution's existing policies and to consider an approach that would mesh them.

"I think it requires a conversation between the IRB and the institutional leaders to say, 'What are you doing? Is it sufficient for what we need to do at the IRB, should we supplement that or can we base our findings of relationships on your data collection?'"

She says there's no one approach that necessarily should apply to every IRB or every institution.

"I think there are a number of different ways this can be handled," Vogeli says "But you need to handle it."

The potential implications of undisclosed conflicts of interest add a sense of urgency to the issue, Vogeli says. She says an IRB doesn't want to approval a protocol on the advice of someone who had an undisclosed relationship and a subject is later injured or dies.

"You can think of a scenario where you would say, it would have been very good if we had known that he had a relationship," she says. "It might have changed the types of questions we would have asked in our review, or the attention that the other members would have paid to it.

"I just think knowledge really helps drive what happens in an IRB, where everybody has the best intentions but you might not ask the questions you would ask if you really knew."

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Tight ship: CAPTN enlists IRB oversight

Early and frequent collaboration key

When they set out to create a research network to conduct clinical trials in the psychiatric care of children and adolescents, researchers at Duke University's Clinical Research Institute (DCRI) knew IRB issues would play a major role.

Many of the solo-practice psychiatrists recruited to be investigators in the network would have no IRB affiliation. And because of the funding level, working with a large central IRB wasn't possible, says **Mark Shapiro**, MA, a management consultant specializing in clinical research and drug development who served on the DCRI research team.

"Ultimately, it boiled down to just being cost-prohibitive for the research network," Shapiro says. "The budget for them to review the network probably would have been equal to the entire budget for the network."

So Duke University Health System's IRB agreed to serve as the IRB of record for investigators who needed one, through the use of unaffiliated investigator agreements. Thanks to the IRB's willingness to take on the project, Shapiro says the Child and Adolescent Psychiatry Trials Network (CAPTN) has successfully undertaken multicenter studies of antidepressant safety in pediatric patients, a comparison study of ADHD treatments and other projects.[1]

Shapiro says one key to the success of the venture was the ability of those creating the network to have multiple face-to-face meetings with IRB officials to work out details. Shapiro says his team probably had about 10 meetings with those officials in the nine months before they got final approval.

"The biggest thing they did to be helpful was that we got face time with the head of the IRB and a couple of his peers," he says. "To basically get a commitment from them that they believed in this research and they would help us work through the kinks in the system. Just getting that support meant a lot."

Managing complexities

The structure of the network created some complexities. Duke determined that the individual practice sites would not be added to Duke's Federalwide Assurance (FWA), so the CAPTN project team helped each site file its own FWA. In addition to serving as the IRB of record for the sites, Duke's IRB also was the IRB for the researchers at the CAPTN coordinating center.

"The structures weren't necessarily in place at the time to manage both things independently and you need to treat the coordinating center differently than you'd treat the sites who were participating," Shapiro says. "Each site needs to be looked at as an individual site — is that facility adequate, have they met the requirements from a clinical and clinical research perspective? And for us at the coordinating center, we had different requirements altogether.

"At the time we were doing this, six years ago, these things were very new, the whole concept of doing research networks," he says.

Research ethics training (including human subjects protection training) modules created by Duke's Trent Center for Bioethics, Humanities and the History of Medicine was made freely available to investigators, many of whom had no previous experience with clinical trials. This was provided in addition to NCI training or to training offered by local IRBs, if an investigator was affiliated with an institution that had one.

The nature of the research provides its own challenges. Because the subjects are children and adolescents, studies developed for the network required Subpart D review, a process Shapiro says the Duke IRB has been helpful in facilitating. "They had some clear policies, we made our case, and they eventually did give at least one of our studies a minimal risk designation," he says.

'High-level discussion'

Shapiro says IRBs contemplating such an arrangement should sit down first with those creating a network and discuss its purposes and scope.

"Really the first step is to have a high-level discussion on the aims of the project — what is the clinical setting going to be? What is the funding? What is the network governance going to be like? You want to see credible people running it.

"In that first interaction, the IRB needs to get a sense of whether it's a worthwhile undertaking," he says. "(At Duke), there had to be willingness to do it, to see it as a worthwhile undertaking. Because clearly from their perspective, that's a lot of additional reviews."

He says that now that the network is in place, the time and effort needed from both investigators and the IRB is much less. And while he says every network is different, he thinks the process of creating new networks may be easier now.

"Once we sort of knocked down those doors at Duke, it was probably easier for other folks who came on with other sorts of research networks in other therapeutic areas to create them," Shapiro says.

Reference

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Software Solutions

Electronic IRB submission integrated for easier use

Paper mountains no more

Electronic IRB submission technology can be of great use to even small research institutions, once it's integrated with existing technology.

"We live in a world of a lot of paper and iron mountains of filing cabinets because protocols can be anywhere from 100 to 500 pages," says **Kimberly Clinton**, CIP, CIM, IRB analyst at Fox Chase Cancer Center in Philadelphia, PA. Fox Chase is a national comprehensive cancer center, and its IRB reviews about 250 protocols per year.

"Every time investigators change a protocol — even one word — they submit a new copy," Clinton adds. "And before long the paper really adds up."

Relying on paper documentation also poses obstacles whenever an institution is audited by sponsors and the federal government, she says.

"It's just overwhelming," Clinton says. "So a lot of institutions, universities are looking to go electronic to manage this whole situation better."

Fox Chase is in an early stage of implementing an electronic system purchased from Click Commerce of Chicago, IL, she notes.

The cancer center is expected to have an increased research workload, so a well-established eIRB program was selected, Clinton says.

"Some products were started in the grant world or in clinical trials management or some other phase of research, and then they're backed into an IRB component," she explains. "But we were not going to purchase a grants or clinical trials module because we have different systems for both of those."

The cancer center's leadership didn't push the IRB to stick with its existing software vendors, so the IRB was free to find a vendor and eIRB system that would best suit the IRB's needs, Clinton says.

Plus, the IRB itself had no home-grown electronic system, which made it simpler to switch from paper to an electronic format.

"Unfortunately, some institutions get stuck because they've already purchased a grants module from a company, and it's kind of decided for them that they'll get the IRB module that matches that system," she says. "And sometimes that's not the best system for it."

The IRB selected Click Commerce as the eIRB vendor because of the company's proven track record and because the IRB has a very active user group with yearly meetings. At these meetings the users can meet with sales people and technical support staff to discuss the problems they're having and to find out when there will be changes to resolve the situation, Clinton says.

"Then once we decided on the product and started the initial phase, we had to create an implementation team," she says. "The team consisted of principal investigators, the information technology department, and IRB staff."

The team's goal was to determine how the switch to eIRB would be implemented and to develop a timeline.

"Right now, we're reviewing all of our forms and procedures and making sure they are following the regulations and are as good as they can be and can translate into the electronic system," Clinton says. "We are doing an internal need analysis of all of our policies and procedures forms."

The institution's information technologies department is handling integrating the eIRB software with existing research software, she notes.

"Another reason we selected Click Commerce is because they have the capability of being integrated with a lot of different things out there," Clinton says. "They're very respectful of our having other systems and say they can feed into whatever we have."

The IRB is helping to design the system by

deciding how much or little they want the eIRB system to do.

"We identify the problems we have in the system now and see if the electronic system will meet those needs," Clinton says. "The answer is not always 'Yes.'"

Once an IRB has the dates for when the eIRB will be up and running, it's time to schedule training meetings and input the skeletal legacy data, Clinton says.

"We'll put some skeletal information in it, and then it will be up to the study team and principal investigator to submit continuing information," Clinton explains. "We'll have a requirement that says that anything new will have to be submitted electronically."

This process will be time-consuming because the information cannot be scanned in.

"Click has smart forms, and the information has to be migrated into the forms for it to collect data," Clinton says.

"The questions we'll need answered are not questions the IRB can go in and answer about our protocols," she adds. "We want them to build this the way the protocol should look in the electronic system, and right now, we're in the early stages."

The cancer center and IRB leadership decided to put in only the principal investigator's name, title, IRB number, the approval date, and the coordinator in the system for legacy data, Clinton says.

"This is enough information for someone to access the protocol," Clinton explains. "And then the PI would be responsible for finishing the submission."

This means some ongoing studies would have many screens that need to be completed, while others would not need that much information, Clinton says.

"It would depend on whether it was a continuing review or an amendment they were putting in," she adds.

Switch is labor intensive

IRBs that intend to make a switch to eIRB should keep in mind that this is a labor intensive project that's piled on top of their regular, labor-intensive work.

"It's a great project to be involved in, but it's really time-consuming when you still have to run the IRB and do your every day work and keeping up with the meeting schedule," Clinton says.

The training sessions will vary from one-on-one sessions to descriptive manuals.

"In the beginning, it will be a challenge for people to learn the new system," Clinton says. "It will be a change for them, and not everybody is embracing that change."

But it's important for IRB directors to maintain a positive outlook and reassure staff and investigators that once they learn the system they can view it at any time and see the status of protocols, she adds.

"It will be very helpful for them," Clinton says. "In the beginning, you usually have a little feedback whenever you're doing something new."

Another consideration is the discomfort of living with both paper and the eIRB data for a number of years.

For instance, the IRB will need to continue to store its existing paper documentation and store closed study information in an offsite location for three years, Clinton says.

"We'll have to fight for space," she adds. "These files take up so much physical space, and our institution wants that space for research, labs, and clinics."

So the transition will be somewhat inconvenient and expensive.

"For a while, we'll have to live in two worlds: the electronic world and the paper world," Clinton says. "We couldn't figure a way around that, so people have to think about it and make arrangements because that's the way it's going to be." ■

Nurture young scientists, invite them to join the IRB

PhD students learn from participation

IRBs often seek new members who are experienced scientists, professors, and medical doctors. But they might be missing an opportunity to educate and engage young scientists by overlooking that pool of potential ethics board members.

A social-behavioral-educational IRB at the Kent School of Social Work of the University of Louisville in Louisville, KY, has encouraged doctoral students to serve as committee members for the past few years.

This has helped to increase the board's membership, and it serves as a valuable way to educate young researchers about human subjects research protection, says **Robert J. Barney**, MSW, PhD-candidate and IRB member at the

University of Louisville.

"This is a novel idea that most people haven't considered," Barney says. "It's worked well at our university, and it could give new direction to a lot of IRBs."

The IRB began inviting doctoral students to serve when the director of the PhD program was an IRB member, Barney says.

"Over the course of looking for new IRB committee members and trying to populate that committee, they discussed using PhD students," he explains. "They've been doing this for a couple of years now — I'm the third PhD student who came on the committee."

Sometimes PhD students are too busy for an obligation like this, but those who agree to be IRB members find it to be a rewarding experience, Barney says.

"It's a definite career boost for the PhD candidate," he says.

IRB participation helps doctoral students, who already have a science background and have begun or might begin to conduct research, thoroughly learn human subjects research regulations. It also teaches them more about how to navigate the IRB process when they have studies of their own to submit.

The university also has a program in which some doctoral students serve as research assistants while they are serving on the IRB. They receive funding to work at the college as an assistant, helping principal investigators fill out their IRB applications. **(See story about research assistant program, right.)**

The IRB recruits doctoral students to serve two years as an alternate member, followed by one year as a full member, Barney says.

"For the first two years while we serve as alternate members, we're learning the regulations of the IRB itself, but we're also learning research courses and building on our knowledge and experience in those areas," Barney says. "You receive a lot of training in the first two years — it's quite a rigorous process."

As alternate members, the students are called to serve on the board only when a full member is absent, he says.

The students often showed up for each meeting, he adds.

Once students become full board members, they participate in protocol discussions.

"Like any other committee member, I'll raise a discussion, questions, and bring forth a consideration of issues on a regular basis," Barney says.

Serving on the board helps doctoral students become more familiar with the IRB, and it reduces their natural tendency to be intimidated when submitting protocols to the board, he notes.

"You begin to have more confidence that the IRB isn't there to inhibit research, but is there to uphold and protect human subjects," Barney says.

"I approach the IRB now with open arms," he adds. "I understand the processes and what will be required, and it gives me confidence that things can be worked out." ■

PhD research assistants help PIs complete IRB submission forms

Paid position educates both sides

The University of Louisville in Louisville, KY, has developed a program that serves as a dual-purpose human subjects research educational program, helping both doctoral students and experienced research professors and others.

A few years ago, the vice president for research started a research assistanceship program for PhD students who have an interest in serving on the IRB and working with principal investigators (PIs), says **Robert J. Barney**, MSW, PhD-candidate and IRB member at the University of Louisville. Barney has been a research assistant for the past three years.

The goal of the program is to provide one doctoral student in the Kent School of Social Work with a paid position that also assists with the student's tuition. In return, the student serves on the IRB and works with researchers as they prepare protocol submissions for the board.

Barney serves as a consultant to researchers, and it complements his role as an IRB member.

"It's an amazing experience," Barney says. "I've done dozens of continuations and amendments and have learned the process of the IRB, while having the experience of interfacing between researchers and the IRB."

So Barney has learned how the decisions are implemented and experienced by researchers.

The research assistant typically works 20 hours per week assisting with any IRB-related matters. This includes helping to build protocols, prepare IRB applications, working with amendments, etc., Barney explains.

"It's through my experience with the IRB that I've learned the applications," he says. "I started as an alternate member of the IRB at the same time I became a research assistant."

The two positions complement one another and helped expedite his learning process, he adds.

When researchers are sent IRB notices, Barney also receives a copy.

"Any time a notice is sent to the PI, it's also sent to me," he says. "I follow up and offer help that way."

Barney also assists with preparing applications and making certain protocols contain all of the correct elements for human subjects research protection.

"I bounce ideas and considerations off the PIs, maybe talking with them about the implications of the research that they may not have considered," he adds. "If there's something they might not have considered, then the IRB might ask for further changes, and I can mitigate some of those requests by the advice I give researchers."

Barney works mainly with new investigators, typically starting by directing them to the educational requirements of the IRB.

"I make sure they understand the processes required by our particular IRB," he says. "We have federally-mandated guidelines, but each IRB is able to interpret those in a unique way and impose a set of requirements unique to that university."

The goal is to get PIs up to speed with the University of Louisville's requirements, he adds.

"I use a lot of informational materials provided by the IRB," Barney explains. "In a lot of cases I look back to the protocols and submissions made in previous years with previous studies to help me understand what was required."

When new issues arise, Barney will compare studies that have the same issues looking for a new twist on an old issue or a new concept that needs to be considered.

"I stay in close contact with the chair and director of the IRB, consulting with them," Barney says. "It's a bit of mentorship that's available to me, as well." ■

NEWS BRIEF

Accredited IRBs fare better during FDA inspections

The Association for the Accreditation of Human Research Projection Programs (AAHRPP) of Washington, DC, has found in an ongoing study that federal investigators find fewer problems in studies conducted at AAHRPP-accredited organizations.

"We have information from an analysis we've done that clinical investigators who have an FDA inspection fare better if their organization is

CNE/CME Objectives

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

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

Physicians and nurses participate in this medical education program by reading the issue, using the provided references for further research, and studying the questions at the end of the issue.

Participants should select what they believe to be the correct answers, then refer to the list of correct answers to test their knowledge. To clarify confusion surrounding any questions answered incorrectly, please consult the source material.

After completing this activity at the end of each semester, you must complete the evaluation form provided and return it in the reply envelope provided to receive a letter of credit. When your evaluation is received, a letter of credit will be mailed to you.

COMING IN FUTURE MONTHS

- Avoid IRB mission creep with this strategy
- Site's compliance audits demonstrate best practices
- Build respect for IRB following these tips
- Interpreting the Genetic Information Nondiscrimination Act for IRBs
- What can IRBs learn from the CTSA sites?

CNE/CME *questions*

21. In examining research practices at the Vanderbilt-Ingram Cancer Center, which process was the slowest?
    A. the IRB
    B. the scientific review board
    C. contracts and grants
    D. continual meetings

22. Pfizer has become the first pharmaceutical company to publicly require central IRBs to do what?
    A. follow the company's approved best practices
    B. become accredited
    C. submit detailed conflict of interest disclosures
    D. all of the above

23. True or False? While IRB chairs surveyed said their members never voted on protocols on which they had a conflict of interest, a third of IRB members from the same group of institutions said they had done so.

24. The benefit to inviting doctoral students to serve on an IRB are which of the following?
    A. provides students with hands-on education of human subjects research protections
    B. provides the IRB with members who have science backgrounds
    C. helps the doctoral student's gain additional experience
    D. All of the above

Answers: 21. C; 22. B; 23. True, 24. D.

accredited," says **Marjorie Speers**, PhD, president and chief executive officer of AAHRPP.

The AAHRPP study has found that a greater percentage of inspections of investigators at accredited organizations resulted in no action from the FDA when compared with inspections of investigators at non-accredited organizations.

For example, of 219 inspections by the FDA's Center for Drug Evaluation and Research, 73% of the 30 inspections involving investigators at accredited organizations indicated no action. By contrast, there were 189 inspections of investigators at unaccredited organizations, and only 53% of these resulted in no action. ■