IRB ADVISOR

Your Practical Guide To Institutional Review Board Management

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Wisconsin's consortium serves as role model for IRB collaboration

Developing trust is challenge

As more research institutions develop collaborations to share IRB reviews, they may find that developing trust is one of the most important and most challenging first steps.

That was part of the wisdom some experts gained from the experience of developing an IRB consortium of different research entities.

"It took time for the institutions and IRBs to get to know each other as individuals and to learn how each operates and what their orientation is," says **Nichelle Cobb**, PhD, director of the health sciences institutional review boards office at the University of Wisconsin–Madison, which is part of a research consortium that includes Aurora Health Care, Marshfield Clinic, and the Medical College of Wisconsin. Two of the institutions have Clinical Translational & Science Award (CTSA) programs. The Wisconsin IRB Consortium (WIC) was launched in January 2009 to allow a central IRB to review multisite research. With several years of work and outcomes available, WIC is a good model for future IRB and CTSA collaborations. The more recently announced CTSA collaboration in Ohio includes major research institutions in Cincinnati, Columbus, and Cleveland, making it potentially a bigger collaboration than WIC, although it is still in its infancy.

"Once we got to know one another we had a greater comfort level," Cobb says. "We could say, 'Yes, they take research protection as seriously as we do and are as knowledgeable, so even if we disagree on some things, we can accept that what you are doing is what you think is right.'"

Building this trust is work. The Wisconsin IRB Consortium built trust through monthly telephone calls, face-to-face meetings, and other discussions between institutions.

"Every time we talk about WIC we say you have to put in

face time," says **Carol Pech**, PhD, associate director of the health sciences IRB office at the University of Wisconsin–Madison.

"You can't just [build trust] by email or a couple of phone calls," Pech adds. "Having meetings is really helpful just to get to know each other and how operations work."

It's also necessary to be transparent about processes and concerns.

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Editorial Questions

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"Every institution has things that are particularly important or peculiar to their institution, and that makes them hesitant to cede oversight to another IRB," Pech explains. "So having those conversations in person over a period of time is necessary."

Another strategy for building trust involves taking time to learn how each IRB conducts its reviews.

"We did a policy review for each IRB, divided by topics," Pech says. "We looked at the policies involving children, going down the line to see if there were major gaps we needed to address or things to work around, and that took some time to do that kind of review and gap analysis."

Compromises are necessary. Institutional officials who are starting an IRB consortium could begin with what Pech calls the lowest common denominator approach, as a first big compromise.

For instance, rather than ask each IRB signing the agreement to have a shared conflicts of interest policy, the consortium could leave those guidelines to each institution, she explains.

"We can tweak things as we go and build out the process as we go along," Pech says. "We're all committed to having a single agreement and just need to know what those basic pieces were."

The key is to start the agreement at a point where all parties feel comfortable, she adds.

The WIC also expects its member institutions to be accredited or, at least, have the policies and procedures in place that could result in accreditation, Cobb notes.

While the fact that an institution was accredited wasn't enough to engender total trust, it is one step an IRB could take to demonstrate that it follows stringent guidelines and is worthy of trust.

One member of WIC is not accredited, but the research staff thinks highly of the institution's research skills.

"It takes some time for institutions to become accredited," Cobb says. "We went through all of the institution's processes and standard operating procedures."

As future research institutions join the WIC, it's likely they will need to be accredited, she adds.

"We have gotten to the point where we would expect anyone joining it to be accredited," Cobb says. "It takes some time for

institutions to do that."

One of the chief benefits of the consortium from the research institution's perspective is how it provides access to a more diverse patient population, says **Chris Sorkness**, PharmD, senior associate executive director for the Institute for Clinical and Translational Research (ICTR), a member of the health sciences IRB, and a professor at the University School of Pharmacy and the School of Medicine and Public Health at the University of Wisconsin–Madison. Sorkness also is a researcher and has used the WIC for some studies.

"From my perspective, whenever you're trying to get universities, organizations, and health care systems to collaborate where they really didn't before, they should remember that it's all about the health care delivery system and its ability to attract patients," Sorkness explains.

The consortium has helped expand multisite research, encouraging investigators to broaden their scope, Pech says.

"I've had researchers come in and say, 'I want to do this study with one of the WIC sites,' and I say, 'Do you know these other institutions are part of this consortium, too?'" Pech says. "And it turns out they didn't know and so then they are willing to expand to another site or two."

Collaboration is good for health care and research business, and it can be done in the context of respect for the culture and history of individual IRBs and institutions, she adds.

Since WIC was founded four years ago, there have been more than 100 studies that have gone through the central IRB process.

"As time went on, each study review got a little bit easier," Sorkness says. ■

WIC experts on forming an IRB consortium

Know your mission

It's probably a good idea to expect more obstacles and delays than imagined when initiating a collaboration for conducting central IRB reviews across a region.

Bringing diverse research institutions to the round table also means bringing their cultures and legal offices along, and these add to the challenges of making a true consortium work, experts say.

Here are some of the ways the Wisconsin IRB Consortium succeeded in developing and implementing a central review process:

• **Decide on a mission or purpose for the consortium:** "The Wisconsin IRB Consortium focuses on the most difficult research — investigator-initiated research," says **Nichelle Cobb**, PhD, director of the health sciences institutional review boards office at the University of Wisconsin–Madison, which is part of a research consortium that includes Aurora Health Care, Marshfield Clinic, and the Medical College of Wisconsin.

"The consortium came about because the University of Wisconsin wanted to bring mutual research throughout the state to improve the health of Wisconsin residents, and they were trying to groom researchers to do this research," Cobb explains.

A central IRB model for a regional consortium of medical research organizations can encourage multicenter research that expands its reach across disciplines and across populations, says **Chris Sorkness**, PharmD, senior associate executive director for the Institute for Clinical and Translational Research (ICTR), a member of the health sciences IRB, and a professor at the University School of Pharmacy and the School of Medicine and Public Health at the University of Wisconsin–Madison.

"Each site has something unique to answer the question best," Sorkness says. "There's a value in doing research not simply at the University of Wisconsin, but reaching out to other populations and other clinicians, as well."

Research consortiums with a central IRB also provide each institution some efficiency benefits, but the bigger picture is how the collaborative effort can benefit an entire state, Sorkness explains.

"The boundaries of the universities are the boundaries of the state," she says. "What the university does should benefit the entire state, and if you believe in that philosophy then it means that we're going to try with our CTSA to get more collaboration across our state."

Better research will result from breaking down institutional barriers, she adds.

• **Conduct broader research:** Having a consortium for multisite research could expand the reach of research, such as asthma studies,

Sorkness notes.

"The asthma populations we could reach in Madison are not as broadly represented as we would like them to be," she says. "With asthma having a greater prevalence and severity in the African-American community, it became obvious to us that we should develop a satellite site in Milwaukee."

The Milwaukee site could use the same central IRB and the same informed consent forms. Having the two sites, and possibly others, as well, also could enrich the research, Sorkness says.

Investigators could look at environmental influences of asthma in urban versus rural versus suburban communities, she adds.

"The issue of resurgent issues that take populations and investigators from Madison, Milwaukee, and Marshfield to answer questions together enriches research and brings together researchers who might not have worked together before," Sorkness says.

With the University of Wisconsin CTSA there is a network of researchers that uses the Wisconsin IRB Consortium. Called the Wisconsin Network for Health Research, the network encourages cross-institutional collaboration through funding studies with merit, she says.

"This is important for investigator-initiated research, and it's at a grassroots level," Sorkness says.

• **Focus on training investigators to improve IRB submissions and protocols:** Early on, researchers demonstrated a lack of experience in going through the central IRB review process, and their applications were bogged down with problems, Cobb recalls.

"Researchers of the investigator-initiated studies didn't have the skills set to work with the IRB, and they didn't know how to write protocols, and there was no existing infrastructure to support them," Cobb explains.

For instance, investigators would describe the study population and situation at one institution but overlook how the multisite study could have differences at other institutions. Their application and protocol would be incomplete, and the IRB would request the additional information, which slowed down the process, she adds.

"We revised our multisite research page in reaction to that, saying, 'This is what you have to have in your protocol,'" Cobb says. "There was not enough guidance in writing protocols for multisite studies, so we put guidance on the multisite webpage, including the required elements, what our expectations are, how they can describe activities in the study, and recruiting subjects at each site."

Researchers who are new to multisite studies still make some mistakes in their IRB review applications, but now they can be emailed guidelines or referred to the website for more information, says **Carol Pech**, PhD, associate director of the health sciences IRB office at the University of Wisconsin–Madison.

"It's not uncommon to get a protocol that describes the overall research, but doesn't describe what is happening at each site," Pech says. "Those are the nitty-gritty things each IRB wants to know before they decide whether to defer review to the central IRB."

"Those are the kinds of things we educate study teams about," she adds. "Researchers who have used WIC before usually have learned what we're looking for."

It also was important to train investigators on how to describe different study populations for each site of a multisite study.

Previously, investigators might list their study population as African-American, which would be accurate for one site. But at a second site the population might be Hmong, and this was not disclosed to the central IRB, although it was important information.

"There could be literacy issues with Hmong elderly who were enrolling, and we needed to have someone in place to interview Hmong participants or to be culturally sensitive to it," Cobb says.

• **Central coordinators are needed:** Investigators are expected to outline how they'll communicate between research sites, and they must identify a central coordinator at each site.

The Wisconsin Network for Health Research program hired a director to provide coordination and guidance to investigators, Cobb notes.

"They hired a study coordinator for a centralized coordinating center, and they started vetting protocols and sending them through their review to make sure they were adequate," Cobb explains. "Then they provide feedback on them and do site initiation visits so each site would know how to execute the protocol."

Each institution in WIC has a designated point-of-contact person. Pech serves as the

designated point of contact for the University of Wisconsin. She coordinates group activities and handles all requests that come through her IRB office. She also was involved more heavily with WIC when the consortium was being developed.

"Multisite studies and questions take up a good chunk of my time," Pech says. "Some weeks it might be over half of my time, but with WIC we also have periods when we don't have a lot of studies and I'll just handle inquiries. So it varies."

Research institutions involved in forming an IRB consortium should be aware that it may require additional staffing or at least some shifts in staff responsibilities.

"I talk to people in other IRB offices and say that it takes time to do this work," Pech says. "No one has a dedicated person just to do WIC, and that's one of the challenges we have as a consortium; we could do lots of things but it takes time and effort, and right now we're all carving this out of our existing positions." ■

BEST PRACTICES SPOTLIGHT

Improving meeting minutes documentation

Address regulatory points in minutes

The cliché about documentation should be a maxim at IRBs, an expert advises: "If you don't document it, you didn't do it."

Documentation is proof, and all IRBs should envision the day when regulators will ask for that proof, says **Cheryl A. Savini**, CIP, principal and chief operating officer for HRP Consulting Group Inc. of Clifton Park, NY.

"When I go into an institution and look at their IRB meeting minutes, my questions are, 'Is the IRB doing what they're supposed to do and having a full discussion of each protocol? Are they going through the regulatory criteria for approval? And are they making the determinations they need to make?'" Savini says. "Are they or aren't they doing that, or are they doing it but the person recording the minutes isn't recording what they're supposed to?"

On the other hand, IRB staff should not record meeting minutes like they are legal transcriptionists, capturing every syllable, she notes.

"Don't go overboard and write 60 pages of minutes," Savini says. "There's a balance there."

Instead, the minutes should be used to document the important regulatory compliance information discussed and add clarity to any issues arising from discussion of a particular study. It's helpful to use a minutes template to ensure that all the necessary information is included in the IRB meeting minutes, Savini recommends. (*See story about minutes template, page 6.*)

"When you're looking for someone to record IRB meeting minutes, you should find someone who is familiar with research terminology as well as medical terminology, if reviewing medical research," Savini suggests. "Also, the person should be trained in human research protection regulations and what documentation is required."

For example, one criterion for study approval is whether subject selection is equitable.

"In order to make this determination, you need to know what the inclusion and exclusion criteria are; who the study is including or excluding and why," she says. "Who is going to benefit and not benefit due to their participation?"

"The regulations state the IRB must make determinations for approval under 45 CFR 111," she says. "It doesn't specifically say that in order to make a determination of equitable selection you have to write down selection criteria, but it only makes sense that you have this information to make that determination."

The goal here is to protect research subjects from exploitation, particularly if they are part of a vulnerable population, Savini explains.

"We don't want researchers going into third-world countries, prisons, dealing with minors or vulnerable populations [only] because they're easily accessible," Savini explains. "The possibility exists that they — the subjects — may suffer the risks and not benefit from the research."

IRBs need to document that reviews address regulatory issues regarding the protocol and informed consent, including but not limited to the following, Savini says:

• **Are risks minimized?** The protocol submitted to the IRB by the researcher should describe the risks and explain how they are minimized, Savini says.

The minutes should record the same information and demonstrate that there is sufficient information for the IRB to determine whether the study's risks are adequately described, she adds.

Here is an example: The principal investigator says there is a risk of headaches, emotional distress, and heart attack in the study being reviewed. At least one member of the IRB should have the expertise to evaluate whether those risks are valid for the type of research being conducted. That reviewer might note that vomiting also is a risk for people taking drugs of a particular class, and note that the investigator had not indicated vomiting as a risk. All of this should be recorded in the minutes, she explains.

The IRB would then decide whether this risk must be added to the protocol and to the informed consent document provided to the subjects, she adds.

Risk is based on both the magnitude of a possible harm and the likelihood of that harm occurring. When an investigator lists a risk, such as emotional distress, for example, it is important to indicate whether the likelihood of this risk is high or low and how severe the emotional distress might be, Savini says.

"Are you talking about child abuse or domestic violence? Could someone not be screened properly? All of these things come into play when determining the risks/benefit ratio," she says.

"Are there procedures in place to minimize these risks?" she adds.

"You should list how risks are minimized and how the IRB came up with that determination," Savini says.

• **Is there a resolution of controverted issues?** "Are there issues that the members of the IRB disagree on or are having trouble deciding?" Savini says. "If, for example, five people on the IRB mention an issue and two don't understand, those may be considered controverted, so how does the IRB come to a resolution?"

The IRB's decision about a protocol should be based on ethical standards as well as 45 CFR 111. Using the 111 criteria helps the IRB to make solid ethical decisions.

• **Does the protocol include documentation for special circumstances?** "There are times when vulnerable populations are included, and you'll need additional documentation for that," Savini says. "There could be instances when you are going to waive some of the regulatory requirements, and you need justification for that."

An example might be if the IRB is being asked to waive informed consent or documentation of informed consent.

"You may want to waive signed documentation of informed consent in a study that includes domestic violence victims," Savini explains. "The justification for that would be that the signed document could potentially be more harm than good for the subject."

If the signed documentation is kept confidential, it could pose harm because the subject may have a copy that might be discovered by the abusive domestic partner, for instance. Just being in the study could pose harm even without disclosing any individual information.

• **Are conflicts of interest described?** IRBs often deal with conflict of interest issues involving either investigators or IRB members.

"There needs to be documentation in your minutes that the IRB was polled before any protocol discussion about potential conflicts of interest," Savini says. "The person with the conflict of interest can be present at the meeting to provide information, but when the IRB begins to discuss the study, that person should not be there."

The minutes should state that the IRB member or investigator with a conflict of interest left the room, and the voting record should show how many voted for, against, and abstained or were recused because of a conflict of interest, she adds. ■

Expert makes case for using minutes template

Here's why it would help

IRBs should have both a minutes process and a minutes template, an expert says.

"A minutes template would direct the minutes taker to ensure that all of the issues that were discussed are recorded," says **Cheryl A. Savini**,

CIP, principal and chief operating officer for HRP Consulting Group Inc. of Clifton Park, NY.

"IRBs also should have a process — and this is very important — on how to run the IRB meeting," she adds. "This is so the person taking the notes has the ability to document the discussions correctly and provides an opportunity for them to say, 'Hold on a minute — we didn't discuss a particular issue such as equitable subject selection,' which is one of the criteria for approval under the federal regulations."

A process keeps the IRB on track, making certain all of the important decisions and discussions occur.

"In addition to that documentation, the minutes should be very clear on what the investigator will be told," Savini says. "The IRB can determine whether they need clarification, changes to the protocol, or require stipulations; and the minutes should be very clear about exactly what the investigator will see in their review letter."

Think of the IRB meeting minutes as a part of the IRB's history and record, she suggests.

"When regulatory agencies come into an institution to conduct an audit, whether for cause or not, the minutes provide a full history of the IRB's discussions and actions," Savini says. "Two or three years down the road there is documentation of what took place at the meeting."

While a template is helpful in ensuring compliance, it's also important to have the right person taking the meeting minutes, Savini says.

"This should be a person who has experience in human research protection so they understand what the regulatory requirements are and they understand the discussions about the type of research being discussed," she says. "They should know medical terms if reviewing medical research and be a detail-oriented person."

"You could even have several people doing the work; having one person documenting the criteria for approval and one person making changes to the informed consent document," she says. "Another person could keep track of IRB members coming in and out of the room to make sure there is quorum, because if quorum is not met and recorded as proof, then the meeting could be considered invalid."

When creating a template, it's important to customize it for the type of research the IRB sees most often. So if an institution never conducts research that is regulated by the Food and Drug Administration (FDA), then it's unnecessary to include regulatory language for those types of studies, Savini says.

Some basic elements of an IRB meeting minutes, in addition to the regulatory requirements under 45 CFR 46.111, include:

- What time did the meeting start?
- Who is present at the meeting?
- Who is the non-scientific member of the IRB?
- Who is the chair of the IRB?
- Which alternate board members are present and who are they replacing at the meeting?
- Are there members with any conflicts of interest?
- Is there quorum for the meeting to proceed?

Another big issue IRBs should note when creating a minutes template and training staff in writing minutes involves the overall strategy for writing the minutes: "The minutes need to reflect what happens during the meeting — not before and not after," Savini says.

For instance, an IRB might say a research protocol is approvable pending the receipt of additional information. By the time the minutes are drafted and brought back to the IRB for review and acknowledgement, the investigator has submitted the necessary information and the protocol is approved. But it would be a mistake for the minutes to say that the protocol was approved at the meeting when the protocol was actually approved after the meeting, she explains.

"It's a matter of making sure that you don't document something if it didn't happen at the meeting," Savini says. ■

Tips for expanding research programs

Solid staff, education are key

Clinical researchers may be looking to expand their program horizons as some areas of research continue to grow.

"The fastest growing therapeutic area in our community health system research program is cardiovascular research," says **Joan Dorin,**

RPh, director of the WellStar Research Institute in Atlanta. "With the FDA requiring extensive post-market data, our medical device research involving investigational and approved products is growing as well." In addition to conventional drug and device research, researchers are also studying tumor tissue and biological specimens to determine the significance of tissue biomarkers that occur in certain disease states and medical events. "Instead of studying an actual drug, they're studying biochemical reactions that happen during a medical event to determine risk factors and develop novel treatment options," says Dorin.

"There's also an increase in investigator initiated research in our program — physicians asking their own clinical questions, and seeking funding for their studies," Dorin continues. "It's an area of tremendous opportunity. Our physician investigators have important clinical questions and appropriate patient populations, and can structure protocols to find answers that benefit the advancement of medical science as well as the treatment of their patients"

Tips for research programs

Dorin, and **Gary I. Cohen**, MD, medical director, Sandra & Malcolm Berman Cancer Institute at Greater Baltimore Medical Center and member of the American Society of Clinical Oncology board of directors, offer tips for research programs looking to expand to new areas:

• **Find staff members who will best fit your needs.** "It is not optimal to have one staff member trying to negotiate contracts and study budgets, recruit, consent and manage study patients, and maintain regulatory processes and sponsor audits in addition to other job duties", Dorin says. "Having a qualified staff will mitigate negative outcomes."

"Having a principal investigator dedicated to the task of maintaining quality is essentially important," Cohen says. "That means understanding the studies, taking a few courses to learn to be an investigator, avoiding conflicts of interest, and understanding randomization and investigational agents handled by the pharmacy. Being a principal investigator doesn't just mean 'I'll raise my hand and do it' — they have to take it seriously and put in the time commitment in the first year to gain the knowledge base and qualifications to run it properly."

• **When possible, have a centralized research office and always use a qualified IRB.** "Having a centralized department has really helped to streamline the process," Dorin says. "We have a variety of clinical trials in many therapeutic areas. We have staff members who are dedicated to specific types of research based on their expertise."

While WellStar Research Institute has been conducting studies for about 25 years, the research office was centralized in the last 10 years in the wake of federal audits. "Conducting research on human subjects is a serious business with serious repercussions and requires strict adherence to the federal regulations," Dorin says. "We were fortunate — we did not receive warning letters or sanctions, and we learned to incorporate processes to mitigate negative audit outcomes into the building of our infrastructure," Dorin adds.

• **Develop the study budget and how the site will get paid.** "The study budget is important to cover our costs, but it is imperative to the success of our program that we cover the expenses involved in our program," Dorin says.

"We do research for its own values and benefits," Cohen adds. "If you just break even doing research, that might be very satisfying. Profit to me means just making the program work so you're breaking even. If you make a profit, you can spread it out and expand the program or whatever you like."

Cohen suggests beginning with just a few studies that you know you can fill. "Focus on a study that you know you can accrue 6-8 patients in one year," he says. "If you do two or three studies like that and put on 20-25 patients per year, it's a good number to shoot for. You know you can get enough reimbursement for trials to cover the costs. If you have fewer patients accrued, you won't get your investment back."

• **Staff communication and education are key.** "Communication is always a challenge, between physician, research staff, patients, the IRB — everyone," Cohen says. "It's a lot harder to have all these things in a study than to have them on their own."

It can be a particular challenge for hospital nurses, pharmacy staff, and other staff who have never cared for clinical trial patients and are unsure of how to proceed.

"When you're first starting a program in a hospital system, it's a little scary for care providers. There may be resistance because

they're afraid they'll do something wrong, or the patient might not get treated," Dorin says. "There can be misconceptions with clinical trial drugs. It takes constant education to make sure that everyone understands that the investigational product has already been proven to be effective and safe and no one is getting a placebo without also receiving treatment."

"In the pharmacy, if there's an investigational product involving blinding, pharmacists have to step out of their routine," Dorin continues. Sometimes the blinding process is complicated and dispensing requires extensive record-keeping. Nurses on the floors also have to follow extra administration guidelines, and lab personnel may be asked to follow protocol procedures that are different than the usual routines.

• **Recruiting study patients.** WellStar's electronic health records enable its researchers to recruit patients from the health system, rather than relying on physicians to contact researchers with candidates. "Again, having a centralized research office allows us to control and enhance recruitment strategies across the system, while assuring adherence to all regulatory guidelines," Dorin says. "We find the patient first, then we consult with the investigator to discuss eligibility." This approach simplifies the recruitment and consenting process across the system by ensuring the physicians do not have constantly look for qualified patients. "It takes constant communication between physician investigators and the research team, but allows us to reach optimal recruitment goals by taking the burden of patient screening off of the physician"

Recruitment can be a challenge for other programs, particularly with oncology. "What's the likelihood that you're going to see someone with a particular cancer with a certain gene transformation? It's very small," Cohen says. "These are the ones that probably belong in the major cancer centers."

For other studies, "if you have something really innovative, you could send a letter to your colleagues in the area and you could get some patients from that," Cohen says. "Mostly what you need to do is look at what patients you are seeing in your general practice and what can you do about that." ■

IRB protocols, workloads rise in 2012

2013 will be another busy year

The last 12 months have been packed for IRB members. Respondents to *IRB Advisor*'s annual salary survey report that their workloads and working hours are on the rise.

When asked how much workloads have increased, 75% saw a jump in 2012, up 5% from 2011. Forty-two percent say that they work 41-45 hours per week — a 12% increase from 2011. Nearly 6% reported working 65 or more hours weekly.

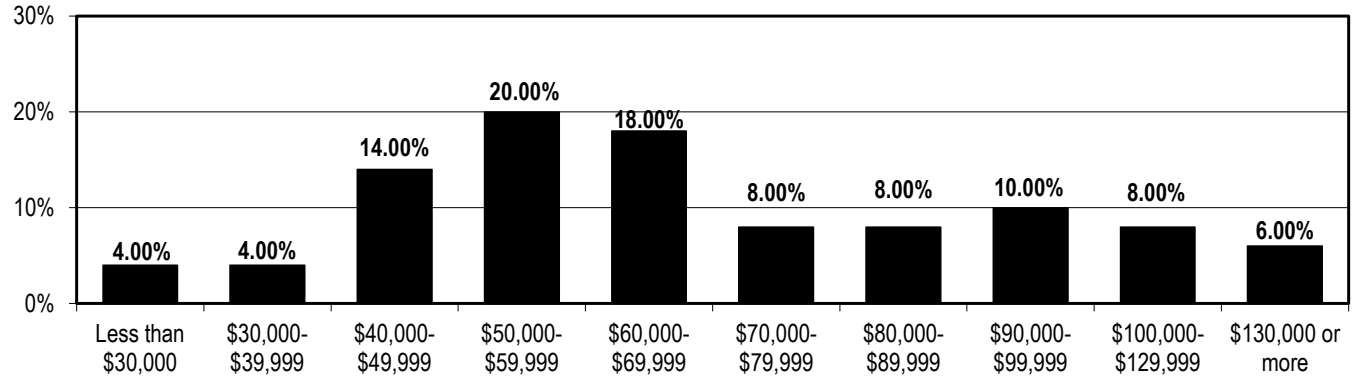
The salary survey also found:

• Most report working in a hospital or academic program — 47% and 49%, respectively.

• A majority of respondents report 4-12 years in the field.

• Sixty-nine percent report no change in staff, while 27% say staff was lost.

What is your annual gross income from your primary health care position?



• Almost 45% have graduate degrees.
• Twenty percent make between $50,000-$59,000, 18% between $60,000-$69,000, and 10% between $90,000-$99,000.
• Eighty-eight percent of respondents were female, most age 46-55.

"Overall, the survey shows that there are a lot of people with quite a few years of experience in the field — and there are more people with graduate degrees," says **Mark Schreiner**, MD, chairman of the committee for protections of human subjects at Children's Hospital of Philadelphia (CHOP), and member of the *IRB Advisor* editorial board.

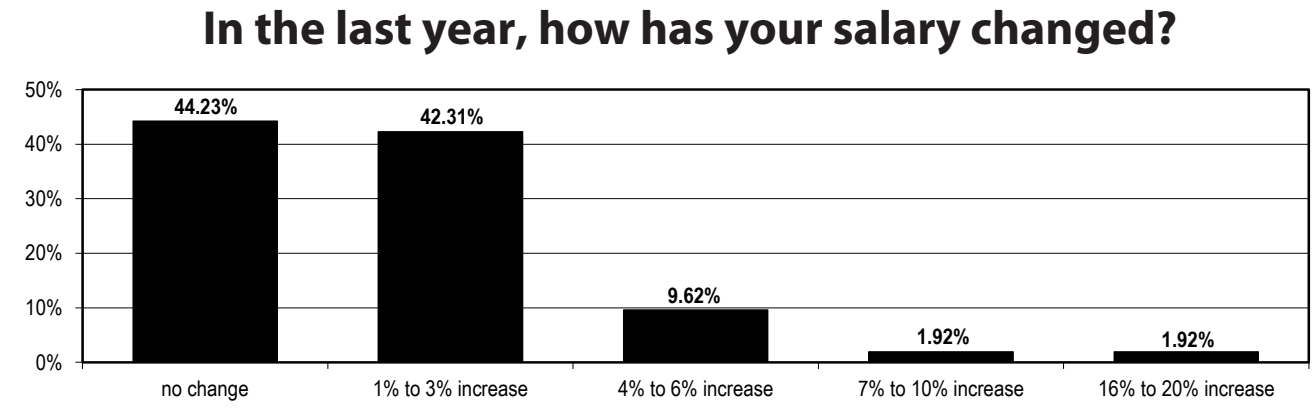
Schreiner is also seeing younger people beginning to emerge in IRBs. "A lot of attendees at national meetings are younger people," he says. "About 80% of our IRB office is made up of people in their late 20s or early 30s."

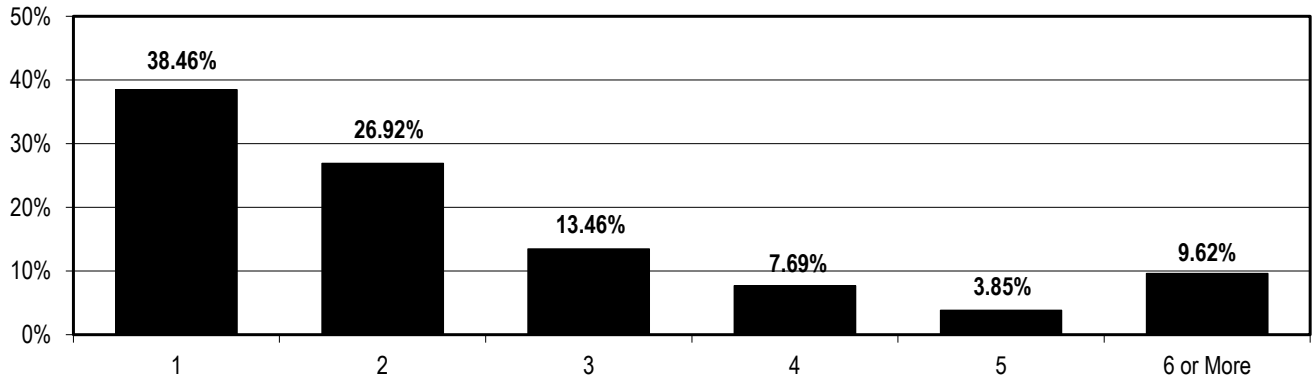
The CHOP IRB is also seeing a growing workload, with a 10% increase in expedited protocol reviews and 3.1% increase in full board reviews last year, continuing the trend of the past 4 or 5 years.

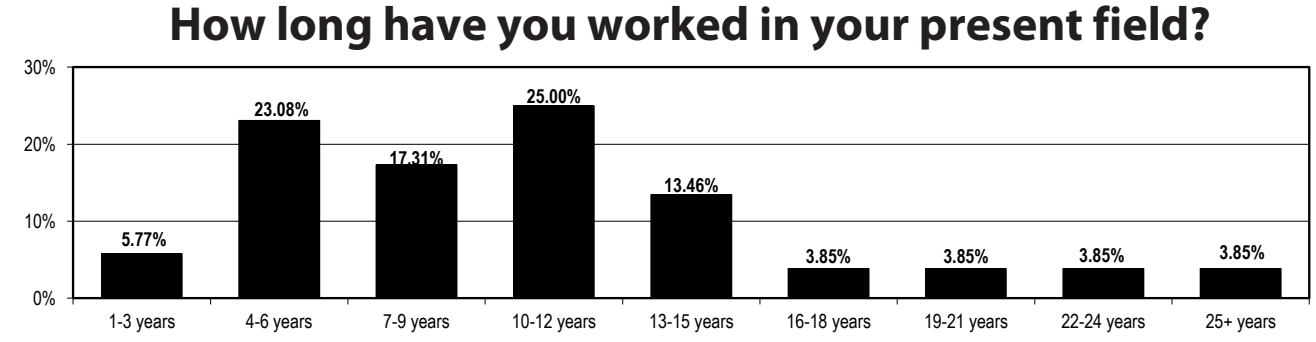
Another busy year

The next 12 months may not be any easier. Schreiner believes the coming year will see greater emphasis on cooperative IRB agreements for multicenter studies and issues related to advances in genomic research.

"One of the things we're starting to see is a greater movement toward cooperative agreements







for multicenter studies," Schreiner says. Funding agencies, he says, are one of the factors behind the shift. "The NIH [National Institutes of Health] seems to be driving this. For several research consortium proposals, our investigators have had to agree in principle to participate with a central IRB in order to be eligible for the grant."

One program in which could serve as a model is the NIH-funded IRBshare, a new shared review model for multisite studies. Institutions use shared review documents and review process under one centralized master agreement and Web portal.

Another driving factor for a shift to multisite studies is to save time and get things going quickly. "Sites can get through the IRB process in as little as a month if they're using a central or fast academic IRB and they have a good contracting department, or it could take as long as 6-9 months or more at other sites," he says. "Nine months is an awful lot of wasted time. I think that if everybody agrees to have a cooperative IRB agreement, we could shorten the time and reduce wasted effort."

There are pros and cons to having a single IRB approve a multicenter study. "A lot of times, one IRB will raise an issue that was missed at other sites," Schreiner says. "If we think a study is a flawed, we need to decide if we are not going to participate, or just accept the flaw. However, when a central IRB finds a problem, it can insist on changes to a flawed study and it is more likely that the study will be fixed."

Hot topic: genome research

The 2013 research spotlight will be on areas related to the advances in genomics, Schreiner predicts. "I think the big discussion will be about genomics and safeguards for genetic information and," he says. Debate will be swirling around confidentiality issues and also trying to define what constitutes a clinically significant result.

"What is a clinically significant result? Is it actionable, and will it help somebody? Will it help someone to know they have a 10% increase in getting a rare cancer by age 80? Researchers and IRBs will have to decide which results could benefit participants' lives, and which make them worse. I think that this is going to be one of the hot area in research ethics."

Confidentiality concerns

Confidentiality of data will also be a big issue in genome research, and clinical research in general, Schreiner says. Concerns will center around what information will be clinically useful and what should be shared — and is a debate, he says, that requires perspective. "The cost of whole-genome sequencing is rapidly dropping and we need to define whether this information requires special protections or not. In the age of Facebook and Twitter, people share all kinds of things. We have given up tons of privacy already and we need to understand what research participants want rather than what we think they want." ■

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

- Collecting metrics can improve QI
- Construct IRB forms that are user-friendly
- FDA issues draft guidance for IRBs, investigators and sponsors
- Research sites can better ensure data security

CNE/CME QUESTIONS

1. When developing an IRB collaboration that will lead to increased central IRB reviews, which of the following is important to building trust between institutions, according to several experts from the Wisconsin IRB Consortium?
   A. Make frequent telephone calls to counterparts at other institutions.
   B. Keep everyone in the loop via emails and text messages.
   C. Put in "face time" through meetings to get to know each person and institution's chief concerns and goals.
   D. Keep a paper trail of mailed letters.

2. Why was it necessary to train investigators about using a central IRB when conducting research that would work for the Wisconsin IRB Consortium?
   A. Investigators often were inexperienced and had difficulty writing protocols.
   B. Investigators might describe the overall research in an IRB application, but they would omit the details of what would happen at each site.
   C. Required elements and other regulatory data often were missing from protocols.
   D. All of the above.

3. When assigning someone to take the IRB meeting minutes, what type of experience or characteristics are most important, according to an IRB consultant and expert?
   A. Hire a legal transcriptionist who can capture every word said at the meeting.
   B. Hire someone who is familiar with research and medical terminology and who is trained in human research protection regulations.
   C. Hire someone who is adept at creating short, concise minutes.
   D. None of the above.

4. When growing a clinical research program, it is important to:
   A. Hire staff who specialize in research regulations.
   B. Begin with a few studies you know you can fill.
   C. Educate hospital nurses and pharmacy staff who may be unsure of how to proceed.
   D. All of the above.