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Your Practical Guide To Institutional Review Board Management

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Data driven: Accreditation group releases metrics for IRB performance

Encouraging `evidence-based' human subjects protection

Using information compiled from its clients, the Association for the Accreditation of Human Research Protection Programs (AAHRPP) is providing an intriguing snapshot of IRB operations.

The data, collected from nearly 200 institutions during 2009, shows the kinds of protocols IRBs are encountering, their workloads, review times and staffing and funding. The goal, says AAHRPP President **Marjorie Speers**, PhD, was to get a sense of what the performance of human research protection programs currently looks like so that institutions can start examining whether they're functioning effectively.

"We undertook this project because we realized there's very little information that exists about IRB performance or performance of human research protection programs," Speers says. "Collecting information is integral to improving quality."

"There has been much discussion lately as part of health care reform about evidence-based medicine. We want to encourage evidence-based human subjects protection."

The information used in the metrics was gathered during AAHRPP's application and renewal processes.

While the accrediting organization's client list isn't completely representative of the IRB community at large — there are few community hospitals among the group, for example — Speers believes the results are generalizable to institutions outside AAHRPP.

And the data can give some hints as to the direction in which human subjects protection is evolving. One example concerns the regulatory agencies that organizations report having oversight over them.

While 86% reported following regulations and guidance from the U.S. Department of Health and Human Services (through the Office for Human Research Protections), 99% reported following Food and Drug Administration regulations and guidance.

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"We're interpreting this to mean that industry-sponsored research is really driving the research enterprise," Speers says. "When we think about what regulatory bodies have the greatest influence over research organizations, it's now the FDA and I think that's a real change."

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Workloads, use of external IRBs

Asked about specific types of research that can be ethically complex, nearly all institutions said they conduct some research with vulnerable populations — 95% conduct research with adults with diminished capacity, 76% with pregnant women, and 71% with children.

"We were surprised the numbers there are as high as they are," Speers says.

The numbers don't necessarily mean that IRBs are conducting drug trials with those vulnerable subjects, however, says **Mark Schreiner**, MD, chairman of the Committee for the Protection of Human Subjects at The Children's Hospital of Philadelphia.

"There could be a lot of research with pregnant women, but it could be surveys or questionnaires," Schreiner says. "I don't know whether it includes the kind of research we'd like to go on with pregnant women, namely studies of the safety and efficacy of drugs."

While AAHRPP does include some large research institutions, as Speers noted, most are smaller organizations. So while the average number of new and continuing protocols overseen by institutions during 2009 was 851, the median number was a much smaller 306.5. Most of those protocols received either expedited or full review — IRBs reported exempting an average of 139 protocols in 2009 (the median was 26.5).

Of the institutions that have their own IRBs, 53% also rely on at least one other IRB for some studies — this could include formal arrangements with an affiliated IRB, a central IRB or an independent IRB. Speers notes that out of that group, nearly three-quarters use an external IRB for less than 10% of their studies.

She says AAHRPP hopes to see the reliance on outside IRBs increase in future years, particularly for multisite studies, as institutions become more comfortable with the idea. Speers says one value of accreditation is that as AAHRPP's standards become more widely known and accepted, it may lead institutions to be more comfortable ceding review to another accredited institution.

Sixty-five percent of organizations reported compensating their IRB chairs, while 42% compensate vice chairs, 34% do so for affiliated IRB members and 57% for nonaffiliated members.

Compensation may take different forms, from direct payments to members to payments to their departments or releasing them from other duties.

"We didn't collect the method of payment — it's an area we want to collect more information on in the future," Speers says.

Schreiner says he'd like to see more information about what percentage of IRB members' time is compensated.

"I'm compensated and my vice chair is compensated for basically all of our time," he says. "But at some institutions, people might get paid for 20% of their time."

Review times – what can they tell us?

The length of time it takes to conduct IRB review has been a point of discussion in the research community. Investigators often blame IRBs for delays in initiating research.

And it's difficult to define what constitutes a "good" review time. Are those who take less time doing a thorough job? Are those who take more time operating efficiently?

While Speers AAHRPP's report doesn't definitively answer those questions, she says it does provide valuable input to the discussion:

- The average time for a protocol to take from submission to review by a convened IRB was 25 days; the average from submission to final approval by a convened IRB was nearly 49 days.
- Expedited and exempt studies proceeded more speedily — average time from submission to final approval for expedited studies was nearly 30 days, and from submission to an exempt determination was about 18 days.

"Is 25 days (from submission to review by an IRB) good or bad? We can't say yet, we don't know," Speers says. "The expedited review is taking about 18 days – could that be shorter? Maybe."

Organizations can look at these numbers and see whether they're falling outside the averages and whether that might suggest some room for improvement, she notes.

But Schreiner says that without further details, the review times, and other metrics from the AAHRPP report, would be difficult to use for benchmarking by individual institutions. With review times, for example, much of the time between submission of a protocol and final approval is spent waiting for an investigator to respond to the IRB's questions or comments.

"I would want to benchmark myself by how long it takes from the time something is submitted until it gets distributed to an analyst for pre-review," he says. "How long before it goes from the analyst to a committee? How long from a committee to a letter? How long after that letter does it then take for the investigator to respond? I'm interested in the internal processes within the IRB that take time."

And he says that other results, including numbers and types of protocols reported, would vary widely by size and type of institution.

"I think that this is a great first step," Schreiner says of the AAHRPP report. "What we need now is to be able to drill down further so we could compare ourselves to (other children's hospitals), organizations like ours doing similar research."

Denise Roe, MSM, CCRP, CIP, RAC, director of the Human Research Protection Program at Vanderbilt University in Nashville, TN, is pleased with the data AAHRPP released. Too often, when someone attempts to pull together information from IRBs, it's with a specific question or hypothesis in mind, which often skews the way questions are presented, she observes.

"With AAHRPP, they weren't trying to answer a question, and I think that's why it makes a difference," Roe says. "AAHRPP isn't saying, 'We think we know a better way.' What they say is 'What is the way that you do it? How is it being done?'"

She said reading the report, gave her ideas for data her institution might track more carefully.

"I actually enjoyed reading their report. It made me think, 'Oh, we should collect that,' or 'That might be another way to look at it.'"

Roe says trying to elicit a lot more detail from the AHRPP client group won't necessarily provide a clear comparison between organizations.

"Because we're not all the same anyway, comprehensive metrics are difficult," she says. "I think if you try to get too specific, you are forming your concept of what it should look like from where you're sitting."

Speers says response to the report so far has been positive. She's already getting requests from clients to collect additional data in future years.

"This is an activity that needs to be driven by the research enterprise," she says. "Then it's going to be valuable to research institutions, to IRBs, to investigators and the public." ■

To view the AAHRPP metrics, visit the organization's website at www.aahrpp.org

Using metrics to track, improve performance

Monitoring review times, training, other measures

To learn the difference collecting and analyzing metrics can make for an IRB, it may be helpful to be a proverbial fly on the wall at the offices of the Vanderbilt University Human Research Protection Program (HRPP).

The Nashville, TN, based institution has been capturing metrics for its IRB since 2001, says Director **Denise Roe**, MSM, CCRP, CIP, RAC. Roe says she

and Associate Director **Julie Ozier**, MHL, CHRC, CIP, don't just refer to the numbers periodically — they use them continuously to track performance.

"We use our metrics, if not on a daily basis, then three or four times a week to make decisions about what we need to do," Roe says. "We really embrace data. It's important to us, it can be the first indicator that there might be an issue that we might want to look further at."

One major indicator that Vanderbilt collects for its four IRB committees is the length of time it takes from submission of a protocol through pre-review to the first committee action letter or approval letter from the IRB.

"We do that for all types of studies, those that have to go to full committee, as well as those that are expedited," Roe says.

That measure, along with monthly metrics about the number and type of new submissions, are published on the Vanderbilt HRPP's website.

She says that while Vanderbilt does collect figures regarding how long it takes until final approval of a study, they aren't published and she and Ozier don't review them as often.

"The metrics are a measurement of how well we're turning things around, *our* response times," she says, noting that the final approval is dependent on many outside factors, including time spent dealing with contracts and managing conflicts of interest.

However, Roe says that the recent release of IRB metrics by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) has caused her to rethink that strategy.

"Seeing that makes me think maybe we should pay more attention to that end result," she says. "It may not be something that we personally at the IRB can change. But perhaps we could be facilitators in other areas to help improve that turnaround time. For example, if I'm waiting for a billing plan to be finalized, is there a way that we can intervene early on and have a discussion with the department of finance to see what their struggles are?"

'Let's not let that happen'

When her office first began using metrics, Roe says, team leaders would examine them monthly to see whether the numbers were staying within pre-established thresholds. If they didn't, "we had to provide a justification — why did this take longer than our target?"

But she says that didn't turn out to be particularly helpful.

"It was happening after the fact — 'why did that happen?' Now we're using more of a 'Let's not let that happen' approach."

She says team leaders now use real-time monitoring to see whether the metrics are getting close to the thresholds, and intervening before that happens.

For example, Vanderbilt has cut the number of lapsed studies by monitoring studies that are getting close to expiring and notifying investigators.

"We'll make a phone call and say 'What can we do to help you?'" Roe says. "Four years ago, we might be sending out four lapsed studies, now we're pretty much down to zero."

The department also used metrics to manage the heavy expedited study workload of its behavioral/social science IRB.

"In their expedited and exempt turnaround time, we'd seen significant time lags for them," Roe says. "If you broke it down and looked at the behavioral/social science team, they were maybe twice as long as the others."

First, she says, they changed the process from two reviewers to one for expedited reviews, which led to an improvement, but the review times still exceeded those of the other committees.

"About a year and a half later, they were still a little high, so we implemented a protocol analyst doing the exempt reviews, and wrote our policies to support that. And they are now right in line with the rest of the other committees as far as turnaround time for expedited and exempt reviews."

Using technology

Obviously this ongoing monitoring requires a sophisticated system to collect data electronically and make numbers available whenever staff needs them.

"We have dashboards, where we can click a button and it will pull all of our data and put it into graphs and pie charts, so we can get an understanding of the performance, all the way down to each staff member," Roe says.

Investigators also can access information about their studies and their training via the Vanderbilt website. When they call up their studies, gauges will tell them how close the study is to expiring and how much time is left before they need to complete their annual training, says **Gene Gallagher**, MSPH, CIP, RAC, VHRPP associate director for compliance and quality improvement.

"We now have fewer incidents when something comes in for continuing review, to have to go back and tell them their training has lapsed," Gallagher says.

Roe says the university's informatics team has been very helpful in making their use of metrics possible. It even has enabled them to link to other departments to get shared measures.

"They really look at integrating throughout the system," she says. "They don't come in and say, 'This is

the system you're going to use.' They say, 'What is your system, and how can we pull information out of it?'

"We've been really fortunate to have some great informatics groups that really work well together." ■

To see the current performance metrics for the Vanderbilt Human Research Protection Program, visit its website at http://www.mc.vanderbilt.edu/irb/metrics/

Avoiding common pitfalls with new electronic system

Hiring IRB/IT specialist is key to success

For many IRBs, the hybrid electronic/paper systems they've used for a half decade or longer are ready to be replaced. Research and medical institutions are moving toward full electronic communication systems, and IRBs will need to make the leap too.

But how do you make the move efficiently and effectively?

A first step is to hire the right person to head up the electronic transformation, says **Philip A. Cola**, MA, vice president of research and technology at the University Hospitals Case Medical Center in Cleveland, OH.

"You definitely need to find someone who is familiar with IRBs, and not just information technology," Cola says.

"You need a person who is a research administrator and who understands IRBs to be dedicated to running the project," Cola advises. "But I don't mean an IRB coordinator who also will be reviewing protocols, running meetings, doing agendas, and writing meeting minutes."

An IRB's coordinators have other duties and should not be asked to shoulder the technology implementation in their scarce spare time.

"We hired a person who had been doing IRB work for another center," Cola says. "When we brought her here we said she wasn't going to do IRB work, but would be building the electronic system with our software vendor."

For a large IRB, like the one at University Hospitals, which has 2,000 active protocols, it also made financial sense to keep this dedicated IRB information systems expert on fulltime once the new electronic IRB system was implemented.

"Our IRB electronic system expert provides information technology (IT) training and education, maintains software with the vendor, and works with our IT people to make sure the technology is working well in our environment," Cola says. "And that's a regular, full-time job."

For smaller IRBs, they might consider hiring a fulltime electronics systems and IRB expert for the implementation period and then shifting the worker to other IRB tasks once the implementation is complete, Cola suggests.

Having a dedicated IT/IRB employee is perhaps the most important step IRBs could take to ensure the smooth implementation of an electronic IRB system. But there are other ways they can do this, as well, and Cola offers these suggestions:

• **Provide inexpensive laptops to IRB members for meetings:** One of the advantages of an electronic IRB system is that IRB meetings can go paperless.

But Cola advises against relying entirely on a large screen with the electronic protocol displayed. Screen navigation at IRB meetings is not the most convenient method for individual IRB members during protocol discussions, Cola notes.

If each member has his or her own inexpensive laptop, just as each typically had their own paper copy of protocol applications, then members could refer to sections in the application more easily and conveniently.

"If an IRB member is talking about a certain part of the protocol, then I can say, 'That's not what I read,' and I could page forward to the section that I remember," Cola says.

"If you're projecting the protocol on a screen that someone in the room is navigating, then you can't double-check it as a member while the conversations are going on," he adds. "With laptops, any member can be anywhere in that agenda at any time, and that's the closest to being paper-based without the paper, so that's why it's important."

• **Phase in electronic implementation:** It's far easier on staff and investigators to implement the electronic system over time.

"Back in November, we said all new protocols after this day must be in the electronic system," Cola says. "But we didn't just one day turn on the switch and say everything you do has to be electronic."

Investigators who had 10 studies and were submitting an 11th to the IRB were required to use the electronic format for their 11th protocol. Any continuing review submissions or amendments needed to be in electronic format. But they were not required to immediately type all existing studies into the electronic system. That process could take place over time, he explains.

"Slowly, but surely, we're converting those 2,000 active protocols to electronic format," Cola adds. "Every submission, no matter what it is in the future, becomes electronic."

This phase-in approach alleviated staff and investigators' fears about not having enough time to make the transition, he notes.

"It was very user friendly to the group, and it allowed us in the research office some time to get used to receiving electronic information and reviewing electronic submissions," Cola says.

• **Expect glitches in data conversion between systems:** Most IRBs use some electronic formats, and the trick will be to convert data in existing systems to the new electronic format.

This is not as easy and straightforward as IRB directors might hope.

"We're a little bit behind in converting some of those pre-existing protocols because there was so much clean-up necessary for the old data," Cola says. "It's an unexpected delay."

The IRB office had been using an old Access database that lacks the formatting necessary for the new electronic system. The new system had field requirements to create a shell for a protocol, and these didn't exist in the old data system, he explains.

The unexpected glitch resulted in the IRB manager having to get involved and spend time and energy on helping to make the conversion.

The protocol information also was stored in paper format, so the office is both converting protocols from the old database to the new system and having staff input paper documents into the new electronic system.

"Some of it is converted if it's clean enough, and some is typed in by a research team," Cola says.

"Data conversion is something you must pay attention to in grand detail from day one," he adds. "I think we did that, and it still wasn't enough to make the transition as smooth as we had hoped."

• **Pilot the transition:** One of the most helpful steps the IRB made was to pilot the new electronic system with five different research teams.

Each of these teams was eager to be involved, and they helped identify problems, questions, issues, and concerns that could be resolved before the system was rolled out to hundreds of people, Cola says.

The pilot testing teams submitted protocols into the system on an unofficial basis and worked their way through the process to IRB approval.

"If they got stuck, we learned together how to fix it so we could help others in the next phase of implementation," Cola says. "People were willing and eager and happy to do that; they were excited to get their hands on the system, so it was a good strategy." ■

Risk: Moving from aversion to management

Create a continuous review process

IRBs should move toward risk management rather than risk aversion, and one way to do this is by obtaining information that provides deeper institutional memory of review outcomes in studies, one expert says.

"One issue is that IRBs are very skilled at imagining the possibility of risk, but we're not basing that assessment on actual data," says **Moira A. Keane**, MA, CIP, executive director in the human research protection program at the University of Minnesota in Minneapolis, MN.

"So the solution would be to look at research as it is implemented," Keane says. "We could take a realistic look at where the risks are and what's actually happening to individuals who participate in research projects."

As IRBs gather this real-time feedback, rather than waiting for the continuing review or a data safety monitoring board (DSMB) report, they'll be better informed about whether or not their decision-making process accomplished its objectives.

"Through the standard continuing review process we get some information on how a study is going, but it's very one-dimensional," Keane notes. "It's a self-report with completed forms and giving the IRB numbers, but it's not the same thing as having a brief conversation with the researcher about how it's going."

Direct communication will lead to a data-driven decision-making process, Keane says.

"We'll make decisions about a new research proposal based on similar proposals in our previous experience," she adds.

"Rather than assuming all the risk we can imagine, [what] is a probable risk for a study? We can say, 'We worried about this in the past, but here's what actually happened,'" Keane explains.

The human research protection program at the University of Minnesota is just beginning to build this type of data-driven making process, she notes.

"We've just begun exploring some possibilities of starting this risk tolerance initiative," Keane says. "We need to assess how and when we'd like to do this because IRBs have limited time."

This approach might also make IRBs more comfortable with studies that pose an unknown type of risk.

"Recently, we had a couple of projects that appeared to be not approvable because of the relative risk," Keane says.

"We worked with researchers and saw that the steps they were taking seemed reasonable, so we let them go ahead," she explains. "But we asked them to come back after they conducted the research and talk with the IRB about the experience to better inform the IRB about reviewing future projects."

This type of communication to advance continuous review of studies could be done in a more formal fashion, she suggests.

Keane offers these ideas for how IRB offices could do such an initiative:

• **Build individual IRB member experience:** Research programs are better served by experienced IRB members who might see a new study and recall that 10 years ago the board had a similar issue arise, and it was resolved in this way, Keane says.

"Some rotation is healthy on an IRB, but I think institutional memory and experience is vital," she says. "We don't have term limits, and if our IRB members are willing to consider serving renewable terms, then that's what we do."

As a result, the IRB's collective experience level is deep, and individual board members can make observations based on outcomes they witnessed with previous studies.

• **Create a continuous review process:** "The continuing review of research projects should be robust enough communication that we can reassure ourselves about our risk assessment and measure whether we overemphasized or under anticipated a particular study's risk," Keane says.

The key is to open the lines of communication with researchers as their studies are underway.

IRBs should encourage investigators to let them know about problems as they occur in the research project and to provide occasional feedback about how the study is doing.

"Some of that can come in post-approval monitoring of research projects when we anticipate they'll have some risk," Keane says.

"We need to look at a study to see if we got the risk and benefit ratio right," she adds.

• **Ask investigators to meet with IRB post-approval:** After a study is approved and one or more subjects have begun to have study visits, it'd be helpful for the investigator to meet with the IRB to provide a report about the initial experiences of research participants, Keane suggests.

And this meeting could take place earlier than the formal continuing review session.

One idea might be to have a researcher meet with the IRB to explain what transpired in the project.

"We spend a lot of time in continuing review looking for the timeliness of reports and looking at whether we're using the right version of a particular document, and that's the easy stuff," Keane says. "This idea is to step back and look at the actual experience that would tell us more about risks."

For instance, IRBs can ask investigators these kinds of questions:

- How were the risks described to subjects?
- Did these adverse events occur?
- How were benefits described?
- Did you see anything that was unexpected?

"The basic experience of individuals informs the IRB," Keane says. "By the time we normally receive that data, we've reviewed dozens of other studies."

• **Think in terms of individual experience, not group outcomes:** Data safety monitoring boards (DSMBs) will analyze data points of high risk clinical trials, but the IRB should be concerned about the experience of individuals in the study, Keane says.

"This is a qualitative approach to reviewing what's going on and not a number-crunching activity," she says. "We want to look at the study and experience of a particular research participant."

The key is to think of ways to formalize this process to obtain qualitative information that can be communicated to the IRB.

"You have to have researchers who are willing to think about these things and to give feedback to the IRB," Keane says. "This information becomes part of a report that is part of the research file, but it'd also be the kind of information that an IRB could draw from when the IRB is assessing risk in future studies."

The goal would be to seamlessly incorporate the risk tolerance process into the IRB's work so in the long run the extra time the IRB spends on mid-study communication with investigators would be offset by shorter review sessions with future challenging studies.

"If we invested the time in this kind of exercise, then we'd get time payoffs down the road when we're reviewing other studies," Keane says. ■

Random audits put the prepare in preparation

Create SOPs for your SOPs

Preparation is key to improving a human subjects protection program, and this could include attending to details, such as creating standard operating procedures (SOPs) for making new SOPs, one

IRB director has found.

When the research protection office at Baystate Health of Springfield, MA, began to prepare for the day it would seek accreditation from the Association for the Accreditation of Human Research Protection Programs (AAHRPP), the first step was to hire an integrity and education specialist and begin an auditing mechanism, says **Karen Christianson**, RN, BSN, CCRP, director of the human research protection program at Baystate Health. Baystate Health received full accreditation in June, 2010.

"Accreditation was a desired conclusion once we had everything in place," she says. "We began the process of auditing both investigators and the IRBs to take a look at where we stood in regards to standards."

The intent was to conduct both for-cause and not-for-cause audits, but Christianson quickly discovered that one auditor could not handle both.

"The random audits were not occurring with the frequency we wanted them to occur," Christianson says. "There always were things that came up and needed to be dealt with on a day-to-day basis."

The organization put in place policies and procedures for reviewing different types of research, as well as new SOPs.

"We rewrote the entire SOPs manual, and put it all in an electronic system," Christianson says. "We took an approach of ripping off the Band-Aid, instead of doing it piecemeal."

Then about a year ago, Baystate Health decided to audit each department with the goal of randomly sampling studies within each department and helping department leaders develop and implement well-written departmental SOPs, based on SOP templates created by the research protection office, she says.

"We developed education specific to that department's needs based on what we found through auditing," Christianson says. "We've been through four of the clinical departments and have five more to go, and that's where we're focused our energy right now."

IC varies by department

The audits helped the research protection office identify and help departments correct mistakes. Most of the problems identified in the departmental audits were misunderstandings of definitions or investigators taking research beyond the scope of IRB approval, but not in a way that impacts risk, she explains.

Also, the audits resulted in SOPs that were customized by each department.

"One department's approach to informed consent may be different from another department's approach," Christianson notes.

Departments send their SOPs to the research protection office for approval after they've made their changes.

The SOP templates are thorough and address a variety of research activities, including these examples: templates on the principal of documentation and case report forms to the consent process and documentation to an SOP on preparing SOPs.

The templates often are one-page long with five main subject heads, including the template's subject, policy, scope, responsibility, and procedure.

For example, the SOP on creating SOPs lists as its policy: "Baystate Health *(department name)* is committed to complying with research related to FDA, OHRP, GCP, and state regulations. It is the policy of the *(department name)* to follow these procedures when developing or amending policies and procedures. This policy describes the preparation and maintenance of the written procedures followed to ensure compliance for research studies conducted in the *(department name)*. This policy also describes procedures for training on policies and documentation of training."

The SOPs template's scope is stated simply as the following: "This policy and procedure applies to the written policies, procedures followed by this research program as it participates in sponsored and investigator initiated research studies."

Under the section for procedure, the SOP lists the following: "Procedure for preparing new SOPs or revising previously issued SOPs:

(Name) or delegate based upon changes to the FDA regulations, guidelines, or research practice, shall write a new policy or revise a previously issued policy that describes the new or revised policy and procedure.

(Name) shall advise *(department head)* research staff conducting research-related activities of newly learned regulations and guidelines as they become available.

Each SOP includes the following in the header:
Department head
Policy Title
Policy number.

Quality control, archiving

"The SOP on principles of documentation includes mechanisms in place for quality control, query resolution, and archiving," Christianson says. "The SOP walks them through ways to approach documentation that are compliant with regulations and guidance."

Researchers conducting investigator-initiated studies particularly have need for this SOP because they don't

have an external body looking over their shoulders, she adds.

Auditors might visit a department and find that all of the sponsored research has detailed and compliant documentation, but the investigator-initiated research is disorganized and lacking in necessary details, she says.

"So if the investigator-initiated studies were audited, we might find they don't have the documentation that's needed," she adds. "Our goal is to get them audit ready."

The audit readiness applies to governmental audits, as well.

For instance, Christianson recommends departments anticipate the issues the Food & Drug Administration (FDA) might address and apply to all SOPs and documentation the acronym ALCOA, which stands for attributable, legible, contemporaneous, original, and accurate.

"So far the weaknesses we've identified are in two areas," she notes. "The first is in documentation for investigator-initiated research, and that's where ALCOA really comes in, and the second is in documentation of the informed consent process."

When departments learn of the internal audit findings, they typically have one point person or a team of people work with the human research protection office staff to go through the audit's findings and the SOP process.

"We have a conversation with the department about everything that is put in place and why, and we provide targeted education," Christianson says.

"If the department is in a good place to start with, and it just needs tweaking to bring it where it needs to be, then we'll communicate that message and document what they've done," she adds.

The final step once new or revised SOPs are approved is to keep these documents alive through period review, Christianson says.

"Once we get them in place, we'll follow up on them," she says.

"Departments like having the structure in place," she notes. "If someone has a question on how long to retain a particular document, then this person can pull up the SOP and not just rely on his or her own memory." ■

NIH studies lacking in community engagement

Survey shows less than half report involvement

As institutions involved in the Clinical and Translational Science Awards program examine how to best incorporate the CTSA's "community engagement" requirement, one CTSA recipient took a hard look at its community involvement practices.

Researchers at Ohio State University who received funding from the National Institutes of Health (which also funds the CTSA) were surveyed about the types of community engagement activities they employed in their studies.

Results showed that fewer than half of NIH-funded studies reported any community engagement. Methods that require more collaboration with the community, such as advisory boards, were particularly uncommon.

Nancy Hood, MPH, who at the time of the survey was community engagement program manager for the OSU Center for Clinical and Translational Science in Columbus, says the goal of the survey was to establish a baseline for community engagement in NIH research.

"We made a specific decision to focus on NIH-funded research, because the CTSAs are NIH-funded," Hood says, noting that community engagement activity would have been much higher had other types of research been included. "We know generally that more community-engaged research is done outside of NIH-funded research."

She believes OSU's results are fairly representative of those of other institutions.

"I don't think we're particularly ahead of or behind the curve," Hood says.

Levels of engagement

Hood's group conducted an online survey of principal investigators for studies whose NIH grants were active beginning in January 2004 and which had been completed by December 2008.

"We wanted studies that were complete, so people were telling us what they did, not what they planned to do," she says.

Surveys were completed for 122 studies. Of that number, 52, or 43%, reported some type of community engagement:

• 21 studies (17.2%) reported either working with an advisory board or committee of community representatives or taking some other action to get input from community representatives during the study. These were described as "Level 1" activities, consistent with the principles of community-based participatory research (CBPR), which calls for a collaborative, equitable partnership between researchers and the communities they study.

• 48 studies (39.3%) reported "Level 2" activities — those that didn't require significant collaboration with the community but still could provide community input. The most common Level 2 activities reported were conducting data collection somewhere other than the main campus and disseminating research results to community representatives.

Other Level 2 activities included conducting focus groups, developing a memorandum of understanding or agreement with an outside community group and holding special events or recognition for study participants.

Hood says that while she had expected slightly higher numbers for community engagement activities, the results reflect the conversation that institutions are having about community engagement in NIH studies, which can look very different from the classic CBPR more commonly seen in public health or environmental health research.

"That was one of the purposes of this study, to call attention to the fact that in the more clinical-type research that NIH is funding there's less of this going on," she says. "And I think we are being critical about what exactly does community engagement look like in clinical research? Does it have to be CBPR or can it be things like service learning and community service and those sorts of things?"

"It's OK if the answer is it's a little bit different from the CBPR model," Hood says. "We just have to keep asking the questions."

Improving the survey

Hood says she hopes future surveys will give respondents more varied examples of community engagement to report, since this survey may have missed some types of community involvement currently in use.

"Do investigators give presentations about their work – if their area of research is diabetes, do they go and give presentations about diabetes in the community?" she says. "Do they engage their students in service learning around the research that they're doing? I think that could definitely broaden the scope of how we're defining community engagement in research."

Hood also expects that future surveys will ask about non-NIH funded research.

"At our university and others, there's a lot of other community-engaged research going on that's not NIH funded and I don't want to short-change that," Hood says. "We want to document that piece as well. It's harder to define your sample when you go outside (NIH funding) because there are so many different funding sources and so many different colleges."

She says IRBs can play a key role in facilitating community-engaged research:

• By fully integrating their own community members into reviews;

• By approving appropriate training for community partners who participate in data collection. Hood says often the usual human research protection training doesn't work for community partners.

"In the typical training that we have here for investigators, the language really isn't appropriate," she says. "There are a couple of excellent online training curricula that I've seen, and I'm eager to look for opportunities to test those training materials. That's something that IRBs will have to address, because it has to be an approved curriculum."

• By understanding the different route that community engaged research can sometimes take.

"Sometimes you can't say exactly at the beginning how the process will evolve, which is different from the typical research process that IRBs are often set up to review and approve."

REFERENCE

Hood NE, et al. Survey of Community Engagement in NIH-Funded Research. *Clin Trans Sci*. 2010; 3:19–22 . ■

Working as team boots community engagement

IRBs can't do it alone

While considering the "community" in community-engaged research may add new issues for IRBs to consider, they're not in this job alone.

Lainie Freedman Ross, MD, PhD, a professor of clinical medical ethics at the University of Chicago says that the nine key functions of human subjects protection are ideally performed by a team of players that includes representatives from the community.

Among them: Investigators, conflict of interest committees, research ethics consultation programs, research subject advocacy programs, data safety monitoring plans (and committees, in some cases) and community advisory boards (CABs).

In a paper published recently in the *Journal of Empirical Research on Human Research Ethics*, Ross and her colleagues delineate the potential roles of all of these groups in ensuring protection of both individuals and communities.

Recommendations specifically for IRBs reviewing community-engaged research include:

• **Minimizing risk –** IRBs can work with CABs to help determine whether a formal data safety monitoring plan is necessary and whether there should be explicit stopping rules.

• **Determining the risk-to-benefit ratio –** Here, the IRB's role is key, although it may consult with other entities, including the CAB, to identify potential risks and benefits, especially to the community. IRBs should revisit this issue on continuing review to make sure emerging risks are identified.

• **Fair selection of subjects –** IRBs can work with CABs to ensure that their perspective is included on this issue. They also help determine whether vulnerable groups should be included, based on potential benefits to those groups.

• **Informed consent, training of research personnel –** In addition to its mandated role of ensuring all required elements of informed consent are present, the IRB can mandate human subjects protection training for any research personnel.

Ross says proper training is especially important in studies that enlist community volunteers to recruit their neighbors. She says one unresolved issue is who should be responsible for monitoring the process to make sure that consent is voluntary and informed.

"IRBs are not required to monitor consent, but from a broader human subjects protection standpoint, we really need to be thinking about how we monitor the things we're asking for," she says. "When we take this into the community and we train lay people to get consent from their peers, whose responsibility is it to monitor and insure that risks and benefits and alternatives are being clearly articulated?"

• **Data monitoring –**While fulfilling its normal role in reviewing adverse events, the IRB should also consider in its continuing review whether the risk-benefit ratio has changed.

• **Privacy and confidentiality –** As in all research it reviews, the IRB must ensure there are sufficient safeguards of participants' privacy and that the data is secure. In community research, it's important that community members who aid in data collection be trained so that they understand privacy and confidentiality issues.

• **Conflicts of interest –** IRBs should insist on a conflict-of-interest management plan to oversee any reported conflicts. They should be aware that these conflicts may apply to both researchers and to the community partners.

• **Vulnerable populations –**IRB should consider whether the community partner involved in a proposed study is accurately representing those of its members who may be in vulnerable populations.

REFERENCE

Ross LF, et al. Nine Key Functions for a Human Subjects Protection Program for Community-Engaged Research: Points to Consider. *J Empir Res Hum Res Ethics*. 2010 Mar;5(1):33-47. ■

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

■ IRB's office training program creates optimal teamwork

■ Improve your IRB electronic filing

■ Innovative approach to recruiting subjects with genetic conditions

■ Role of IRBs in improving efficiency in a research network

CNE/CME QUESTIONS

13. Whose regulations and guidance were most often followed by institutions included in AAHRPP's metrics for human subjects protection programs?
A. The U.S. Department of Health and Human Services
B. The Food and Drug Administration
C. The Department of Defense
D. The International Conference on Harmonization

14. More than half of the AAHRPP institutions relied on at least one other external IRB for reviews of some studies. What percentage of their research did most of them report using an outside IRB to review?
A. Less than 10%
B. 25%
C. 50%
D. More than 90%

15. What is one of the chief obstacles to a smooth transition between an existing electronic IRB system and a new electronic IRB system?
A. The old system lacks the formatting necessary for the new system
B. The old data needs extensive clean-up work
C. Some old systems were handled with paper format storage, and these need to be converted to the new electronic system
D. All of the above

16. Human research protection offices might conduct departmental audits for the purpose of which of the following:
A. To make sure all departments are following precisely the same SOPs written at the institutional level
B. To give departments an opportunity to write new or improve old SOPs, following a template, and to identify their regulatory weak spots that can be addressed through education
C. For the purpose of giving auditors practice
D. All of the above

Answers: 13. B; 14. A; 15. D; 16. B