IRB ADVISOR

Your Practical Guide To Institutional Review Board Management

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QI projects aim to prevent problems, improve processes

Use a QI feedback loop

The best quality improvement (QI) projects at research institutions have multiple goals and can quickly identify problematic trends while also preventing regulatory noncompliance. They can improve IRB and investigator education and training. They can make existing processes more efficient and revamp IRB forms and templates. They also can be seen as beneficial to the whole research experience, rather than being viewed simply as punitive.

How do they achieve all of these objectives?

A first step is to frame the QI program in a constructive way, experts say.

For instance, call the oversight process "study review" instead of "audits," says **Susie Corl**, MSW, MPH, CIP, CCRP, quality improvement specialist at Boston Children's Hospital's office of clinical investigation, Education and Quality Improvement program (EQuIP).

"We look at principal investigators and their research and how it's going, and we give individual feedback," Corl says. "We give a report to the investigator, and it's confidential."

Data from these reports are used to identify noncompliance trends or problems serious enough to require reporting them to the IRB or regulatory agencies. But the typical minor findings are given only to the research site.

"We make sure the IRB doesn't know about the reviews and findings," Corl explains. "The only caveat is if we go out and find that someone is doing something that puts subjects at risk."

IRB New Year's Resolution: Focus on QI

[Editor's note: Quality improvement would be a good activity for every IRB to include in its goals for 2014. So for the New Year, **IRB Advisor** *offers this look at how some human research protection program leaders nationwide are initiating and implementing quality improvement processes.]*

Corl calls it a "feedback loop," which means the information is used to educate researchers about problem areas and what they can do to fix and prevent these issues.

Educating both IRB members and investigators is another significant step toward improving a QI program.

"I always tell people you have to have some education in there to enable the improvement to happen and to show how you are a support mechanism for investigators," says **Sarah White**, MPH, CIP, director of the human research quality improvement program at Partners HealthCare in Boston.

Partners HealthCare has a quality improvement program with a particularly strong focus on education, White says.

"The scope of our QI program is larger than some others," White says. "We focus on ensuring compliance with components of research and educating investigators; we range from auditing or onsite reviews, as we like to call them — both for-cause and not-for-cause, and doing education at a study start-up."

Partners HealthCare QI program also works with investigators whose work is subject to Food and Drug Administration (FDA) rules to assist them and educate them about registering with the federal site ClinicalTrials.gov.

"We assist investigators in understanding and doing an analysis of whether they need to register and how to understand the results," White says.

Research institutions need both the auditing/review oversight piece and the education piece, she notes.

"You need the study review to understand what's going on in the field," she adds. "You need education to improve the quality of research documentation and compliance on site."

On-site reviews can be a rich source of QI data, but they need to be conducted consistently and systematically to be useful, White observes. White spoke about setting up quality improvement programs at the 2013 Advancing Ethical Research Conference, held by Public Responsibility in Medicine and Research (PRIM&R), Nov. 7-9, 2013, in Boston.

To improve the data-mining possibilities of on-site reviews, White led an initiative to develop a database and observation index for use by all reviewers. The observation index lists more than 100 different observations that may be made at an on-site review. It links observations to a regulatory reference and corrective action, and it ensures consistency across the review team and from site to site and review to review, White explains. *(See story about Partners' observation index, page 4.)*

"The database is one of those behind-the-scenes tools that has made the Partners quality improvement program very efficient and very consistent," White adds.

Once the QI process identifies a problem, the

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next step is to provide feedback to the research site and to develop a plan for corrective action and continuous monitoring, Corl says.

"The one thing we need to be really careful about is whether to close out the issue or provide continuous monitoring after we give feedback to the director and we get a response," she explains. "It's complicated."

Corl presented a poster at the PRIM&R meeting about a QI project in which continuous monitoring proved to be very important to improving not only one research site's human research protection activities, but the entire program's processes. In this case, an on-site review discovered discrepancies in how some informed consent forms were signed. But through a more in-depth investigation and continuous monitoring, Corl and the QI team also found that the problem was systemic due to a problem with the IRB-approved template for informed consent. (*See story about improving IC signature documentation on this page.*)

Continuous monitoring of specific problems contributes to the feedback loop, Corl explains.

For instance, when a review showed that one research site only had one parent permission signature on its informed consent forms that require two signatures, the QI office asked the investigator to correct the problem and then went a step further by reporting the issue to the director of research compliance, who decided they should review all IRB records to see if there might be a trend involving missing parent permission signatures on IC forms, she says.

"This was the feedback loop," Corl says. "We reported the problem to the director, did a larger report on the findings and then gave that back."

Then the QI office shared information about an identified trend with the IRB and continued to look, intermittently, at records to make certain the suggested changes were made and that they resulted in compliance, she adds.

The resulting efforts led to a QI project that improved the overall research protection program, while preventing what might have been an unfair focus on a single site's noncompliance issues.

"I find that in this role of QI at the institution, we are able to focus heavily on education and then use the knowledge we've gained to do the reviews," Corl says. "Even if we find minor problems, it's still important in the long run, and we're gathering information that we can share with principal investigators." ■

IRB New Year's Resolution: Focus on QI

QI review finds problem with IRB's IC form

Solution is multifaceted

An informed consent form with two parent signatures is an IRB requirement of some studies at Boston Children's Hospital. But when a study review found that one research office was failing to meet this requirement, the resulting quality improvement (QI) investigation turned up a trend and an even bigger problem: The IRB's approved informed consent (IC) form made it difficult to obtain those two required signatures.

The Education and Quality Improvement Program (EQuIP) found that only one signature was obtained during a routine, not-for-cause study review of an investigator's files. The EQuIP reviewer also found that even when there was a second parent present during the IC process, there wasn't a place on the IC form for that second parent's signature.[1]

Plus, some research staff were unaware that the second signature was required, although the IRB specified the requirement in the initial IRB approval letter.[1]

"We saw the problem of the consent form not being formatted correctly, and we thought it could be a bigger problem," says **Susie Corl**, MSW, MPH, CIP, CCRP, quality improvement specialist at Boston Children's Hospital's EQuIP.

The EQuIP findings at the single site led to a review of IC forms at all sites to determine whether this two-signature noncompliance was a systematic trend.

"We saw that it was a bigger problem, so we took it to the IRB after all the studies were reviewed," Corl says.

Through the QI process, EQuIP staff discovered a trend that was immediately addressed and fixed. Here's how it worked:

1. Identifying a problem through not-for-cause on-site reviews: Conducting routine, not-for-cause audits/reviews is essential to research compliance, but these also are crucial to identifying cultural, systemic, workflow problems that can lead to inefficiencies and regulatory issues, Corl says.

Besides looking at investigators' work, EQuIP reviews the IRB's work, creating an Excel spreadsheet based on identified issues, she

explains.

When a research site is reviewed, the results are kept confidential and not released to the IRB, except in rare circumstances of subjects being placed at risk, she adds.

The promise of confidentiality has been instrumental in building trust between researchers and the research protection program, Corl notes.

"We want to be seen as an educational resource for principal investigators," Corl says. "But we keep track of who didn't do something correctly."

The findings are placed in a database where they are compiled to identify trends. If one site has a recurring problem, then perhaps other sites are experiencing the same issue. This was how the EQuIP office identified a trend of sites not obtaining second parent signatures when required to do so by the IRB.

On-site reviewers found the problem at one research site and quickly realized it might not be an isolated incident. They reported the problem to the site's PI confidentially, requiring a summary of corrective actions taken. But they also took an additional step to address the bigger issue of a systemwide problem.

"We considered it a bigger concern that could result in pretty big regulatory noncompliance," Corl recalls.

2. Report suspected systemic problem to leadership: When the EQuIP office found that one site had repeated problems with obtaining second parent signatures, the office sent their findings and suspicions to the director of research compliance, who asked that they conduct an internal audit of all studies to see if other sites also were omitting the second parent signature, Corl says.

The systemwide review revealed a problem with the two-parent permission documentation at more sites, Corl says.

There was an inconsistency between the IRB's two-parent permission determination, as stated in the IRB minutes and approval letter, and in the IRB's informed consent format, which had room for only one signature.[1]

3. Give findings to IRB and leadership: The EQuIP office reported its findings to the research compliance director, recommending the consent template signature section be reformatted to facilitate compliance. They also sent the report to the IRB at the director's request.

"There were a number of studies where the IRB made a two-party determination, and it was something that could have resulted in confusion," Corl says.

4. IRB implements response and solution: The research compliance director had the IRB change its practices and policies to resolve the issue. One change was to revise the consent form template to make it easier for investigators to document the second signature or to use a check box if the second parent wasn't there, Corl explains.

5. Follow up and monitor: Once corrective actions are made, it's important to follow up and monitor to see that these are done correctly and to see that the changes result in optimal compliance, Corl says.

EQuIP reviewers will schedule a follow-up every six months to analyze the corrective action plan and make certain it's being implemented effectively, she adds.

"I think the quality improvement process worked well," Corl adds.

Part of its success is due to how well integrated QI and research compliance are with the IRB, she notes.

"Since we go to IRB meetings and are somewhat connected to the IRB, we understand IRB work."

REFERENCE

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IRB New Year's Resolution: Focus on QI

Observation index ensures efficient audit

Site issues easily tracked, measured

Research protection programs that conduct audits or on-site reviews for monitoring compliance typically collect a wealth of information about research practices and trends. However, the wealth often remains untapped because the review comments and findings are left in individual data silos.

The key to making this information work for a research program is to collect information that can be generalized, using analyses that can translate from one review to the next.

The quality improvement program at Partners HealthCare in Boston developed a tool to mine these data. Called an observation index, the tool contains more than 100 different observations that can be made by an on-site reviewer, says **Sarah White**, MPH, CIP, director of the human research QI program at Partners HealthCare.

"The QI teams are collecting such great information that it seems like a no-brainer to have a database for storing all of this stuff," White says.

The electronic tool has cut the time on-site review specialists spend on writing reports down to two or three hours from five or six, White says.

"It was a significant time saver and enabled us to be more efficient and do more audits," she says. "Also, it enabled us to do more education."

The database contains the itemized observations made during on-site reviews.

"It's a standardized index of observations we might make during an on-site visit," White says. "For instance, one is that the study rep has not signed a consent form or that a consent form is missing."

The data collected from the observations makes it possible for the institution to track its activities and see how many IRB request reviews have occurred. They also can see how much time is spent with any particular research group and generate information about where there is a need for additional training and information, she adds.

Other observations involve broad categories of observations related to federal regulations, the institution's policies, and good clinical practice guidelines. Here are several more observations on the index:

• **Study documentation has been inappropriately obscured.**

• **Exceptions to inclusion and exclusion criteria have been made for subjects.** There is no documentation that these exceptions were submitted to the IRB.

• **Subject dates are not documented on all the consent forms.**

"Because it's broad and somewhat generic, the specialist will make an observation and put it in a bucket, and then we can query back into those buckets and see how many times this [finding] occurred," White explains.

With data from the itemized observations, the QI program can assess whether to make system changes, such as revamping a policy or improving education, she adds.

Before creating the index, the standard practice was to write reports in Word, change them to PDF files, and send the files to investigators without storing and categorizing any of the findings in a database, White says.

"We'd have to scramble and cobble things together to get the information we needed, and now all we have to do is put in a query, and the information comes out," White says. "It's great."

The observations are organized according to topics, such as "study staff training" and "adverse events." QI specialists provide the detail to the broad observation in the actual report to the investigator. Examples might include:

• **Training:** There is no documentation that study staff have been trained on the protocol.

• **Adverse Events:** Tracking, assessment, and/or reporting of adverse events to the IRB and/or sponsor is not adequately documented.

Each of these observations also has a column for the applicable regulatory reference. The QI program references federal regulations, institutional policy/guidance and ICH Good Clinical Practice. Examples of these from the Partners' index include:

• The investigator should ensure that all persons assisting with the trial are adequately informed about the protocol, the investigational products, and their trial-related duties and functions. [Partners Guidance: Principal Investigator's Responsibilities; GCP 4.2.4]

• The principal investigator is responsible for documenting and reporting adverse events in accordance with institutional policies, federal regulations and good clinical practice guidelines. [Partners Policy; Adverse Event Reporting; GCP 4.11.1]

A final column is for suggested corrective actions, including these:

• **Document study staff training.**

• **Obtain documentation and/or report adverse events as applicable. A log can be used to ensure adverse events are reported in a timely manner.** A template can be found on the Partners' website.

The index has multiple uses, White notes.

"As far as trends we can identify by use of the database, we can identify a common observation, make a systematic change, such as a clarification in a policy, and track how/if that systematic change worked," she says.

Creating an observation index is a long-term time saver, and it opens up many possibilities for a more efficient human research protection process and program, but it does require a significant up-front commitment of time and

resources, White notes.

"It was a huge undertaking," she says. "I would say there were two of us over several months who were really looking at this thing and developing it from our knowledge and observations over the years."

The QI team also referred to federal regulations to develop some of the general observations.

"If I opened the federal regulations and looked at what a clinical investigator is responsible for, like ensuring the subject receives a copy of the informed consent, then that became an observation in a broad category, and that went into the index," White explains.

"It's important to point out that we use that index as a means to track and analyze data, but once a report is generated from the database, the specialists go in and include more details of the findings," she adds. "For example, the generic observation might be 'study procedures were changed without IRB approval'; in the report, the analyst would identify how the survey questionnaire and blood test were not collected."

Once the QI team compiled a long list of general observations, an analyst and data expert took the information and adapted it for an electronic checklist that is flexible enough that new observations can be added as necessary, White says.

The electronic observation index is user-friendly, she notes.

"When specialists come back from an audit, they plug in all the observations they made into our database, which houses the index, and it generates a report in Word," White explains. "Then they go in and insert their details; I review the report and it is complete." ■

IRB creates user-friendly chart review application

Approval time dropped 10-plus days

When an IRB process is routinely misunderstood and cumbersome, it might be time to ask the users what they think would work better.

At least that's what the human research protection office at the University of California–San Francisco did when planning to revamp the chart review research IRB application. And it worked: The improved application had a post-implementation mean time to approval of 18.6 days, more than 10 days shorter than the pre-implementation mean time of approval of 29.3 days.[1]

Before the changes, the application process had many problems, says **Liz Tioupine**, CIP, iRIS system administrator, human research protection program (HRPP), UCSF.

"We had one chart review study returned six times for corrections," she recalls. "People could not understand what we were asking in our application."

The application's wording was called "IRB speak" by some critics, and IRB analysts found that most submissions for chart review research were poorly prepared, with about 82% of submissions in 2012 returned for corrections and nearly one-quarter returned more than once.[1]

Confusion over the form's questions was so commonplace that the HRPP office could only conclude that the application was not user-friendly, Tioupine says.

The IRB enlisted help from the form's users, faculty of different clinical research areas, asking them for their thoughts on which questions were confusing and which were unnecessary.

The IRB and researchers worked together to create a streamlined chart review application form with the goal of making it simple enough for a novice investigator to complete quickly. To achieve this goal, they eliminated 32 unnecessary questions and reworded many others, Tioupine explains.

"We'd read the application to them, and they'd say 'That doesn't make sense for a chart review study,'" Tioupine recalls. "We got rid of questions like, 'State the hypothesis,'" she says. "The study design and hypothesis boiled down to one simple question of 'What do you hope to accomplish with this study?'"

The IRB also asked researchers for help in rewriting questions to get rid of the IRB-speak.

"We had thought the general terms we had for the main application could be applied to all different types of research, including social-behavioral research, and we found that these terms had very specific connotations," Tioupine says.

For example, the IRB found that researchers seemed unclear about how to answer the question regarding inclusion/exclusion criteria.

The original form said, "Describe the inclusion criteria and describe the exclusion criteria."

The IRB had found that researchers often had difficulty with this question, saying it didn't apply to their study because the study involved a chart review and not visits with patients, Tioupine says.

"We asked them, 'How do you decide what charts to look at?' and they would say, 'We're looking for people with high blood pressure who are on two or more medications,'" Tioupine says. "And we'd say, 'Okay, that's what we mean.'"

The researchers' response was to suggest the IRB simply ask for that rather than use the terms "inclusion" and "exclusion," which investigators believe means something very specific, such as the process of screening patients for a clinical trial, she adds.

So the application's question was changed to, "Describe the population being studied."

Here are some examples of other questions on the revised chart review IRB application form:

• What do you hope to accomplish with this study?

• Indicate if the primary study population includes:

- children or neonates;
- pregnant women;
- prisoners;
- none of the above.

• Types of records or biospecimens being reviewed/analyzed:

- medical record or other health record (identify source below);
- data repository (IDR) or The Health Record Data Service (THREDS);
- existing research records (including OnCore) or identifiable biospecimens (identify source below);
- records open to the public (identify source below).

• List all variables you are collecting from the records.

• Approximate number of individuals whose records or biospecimens you will review/analyze. If you cannot estimate the number of records you will need, explain why.

After streamlining and improving the application form, they tested it with a focus group and made fine-tuned adjustments before deploying it in a pilot test system, Tioupine says.

Researchers also helped the IRB realize that the application form needed to address collaborations with outside sites.

"We did not realize that any chart review research could involve other sites, and other sites might rely on us to be their IRB," Tioupine says.

So the form has a section for adding information about collaborating, non-UCSF sites.

Less than a year after the application form was revised, the IRB found a number of positive outcomes, including satisfaction among investigator users, Tioupine notes.

"They all loved it," she said. "The time to complete the new application was within 30 minutes for almost half of the [researchers]."

Specifically, before the new form was implemented, the mean time for creating the application to the time it was submitted was 20.1 days. After the implementation, this time had dropped to 6.8 days.[1]

The process resulting in the improved IRB application proved so successful that the IRB plans to convene other faculty researcher user groups to streamline other types of research processes.[1]

"Without sitting down with researchers and having them ask us, 'What does this mean?' we wouldn't have known what was wrong," Tioupine says.

Since implementing the improvement, Tioupine has shared the revised form with other IRBs, finding considerable interest in it: "One guy sent me his grandmother's marinara sauce recipe as a thank-you," she says.

REFERENCE

1. Tioupine L, Jacoby V, Douglas V, et al. Design and Implementation of a 'researcher user-friendly' chart review research IRB application. Poster presented at the 2013 Advancing Ethical Research Conference, held by Public Responsibility in Medicine and Research (PRIM&R), Nov. 7-9, 2013, in Boston. ■

Staffing, collaborations top IRB issues

Workloads up, staffing unchanged in 2013

The last 12 months have gotten busier for IRBs. The results of *IRB Advisor*'s 2013 salary survey indicate that workloads have increased, while IRB staffing levels have stayed mostly the same.

Fifty-six percent of respondents report an increase in workload, and 74% said personnel levels have not changed. Seventeen percent indicated a decrease in personnel. When asked to name their biggest personnel issues, respondents stated federal furloughs, increased demands for

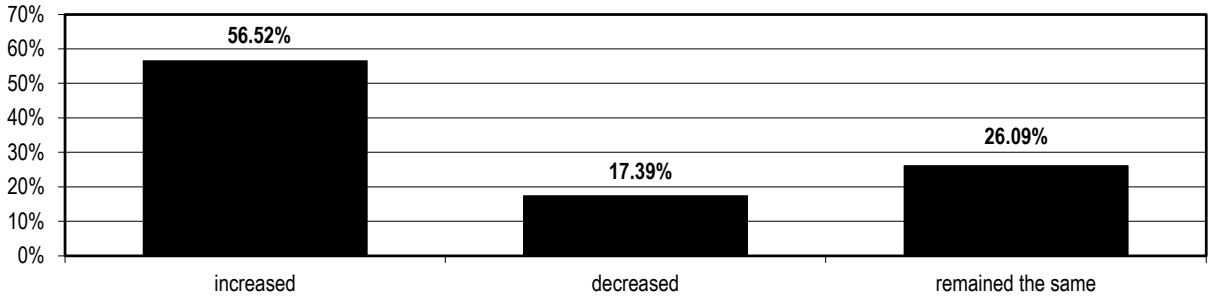
efficiency and quality with few added resources, too much work for the small amount of staff, and lack of appropriate resources and formal training.

"Just because there is an increase in the number of studies reviewed doesn't mean there will be an increase in staffing," says **Kimberly Irvine,** CIP, CIM, executive vice president and chief operating officer of Biomedical Research Alliance of New York (BRANY) in Lake Success. "In the coming year, I expect that there may be decreases. There may be a lot more competition for grants that are available. [At BRANY], we did see a decrease in industry-sponsored studies."

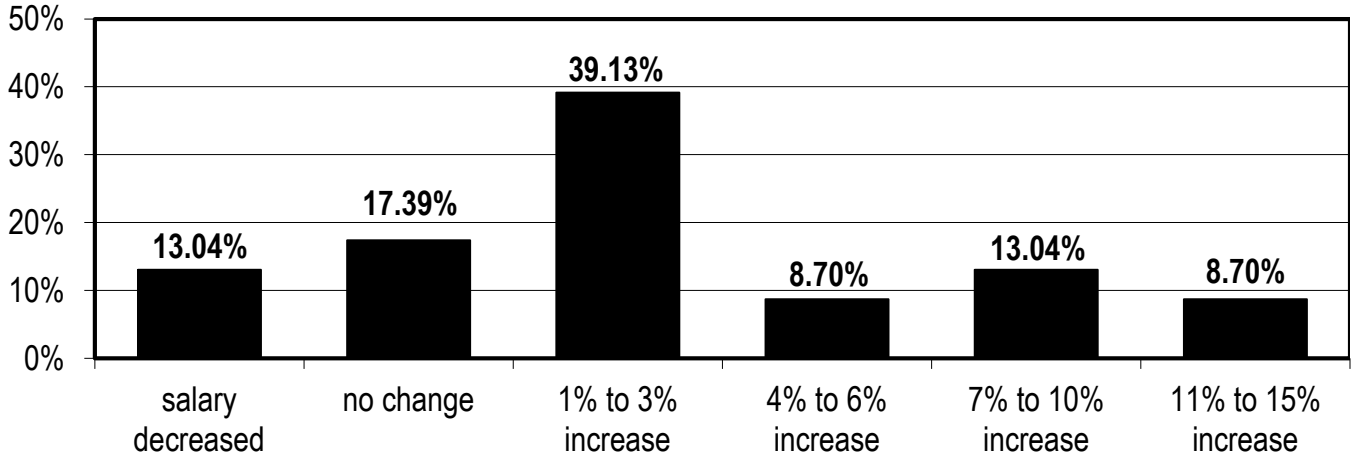
Nearly 60% of respondents said that they supervise staffs of 0-3 people. Lower budgets and funding issues can put a strain on research programs as staff juggle more work, fewer employees, and following institutional and federal regulations. "Retaining staff is increasingly becoming a challenge for IRBs because many can't afford to do it," says **Nichelle Cobb, P**hD, IRB director at the University of Wisconsin—Madison. "The more experienced people you have in your office, the better off you are. They know the regulations and can do really well with advising and complying with the regulations. When you get high turnover, it can be very challenging."

Electronic submission systems may mean that fewer people are needed to handle submissions. "You realize some economies of scale in terms of managing submissions — you might need fewer people reviewing, but still need people to handle customer service and maintenance of the electronic system," adds **Raffaela Hart**, BS, CIP, CIM, vice president of IRB and IBC Services at BRANY. "It may be a wash, depending on how many submissions you get; two people could

How has your workload changed in the last year?



How has your salary changed?



handle them, but you may need one person to handle the system and anything else that didn't exist before."

There was also a greater shift in 2013 toward research institutions using a central IRB for approval, whether an external IRB or part of a larger IRB collaboration. This can help make multisite research approval more efficient and take some of the burden off of IRBs — but it doesn't necessarily mean a reduction in workload. "There have been some papers on whether institutions should allow external IRBs. Some of the takeaway messages were that even though they are using an external IRB for the review, there are still other things that the institution has to do relative to the research that doesn't necessarily free up a person," Hart says. "People may think it'll alleviate the workload, but it will only alleviate some of that."

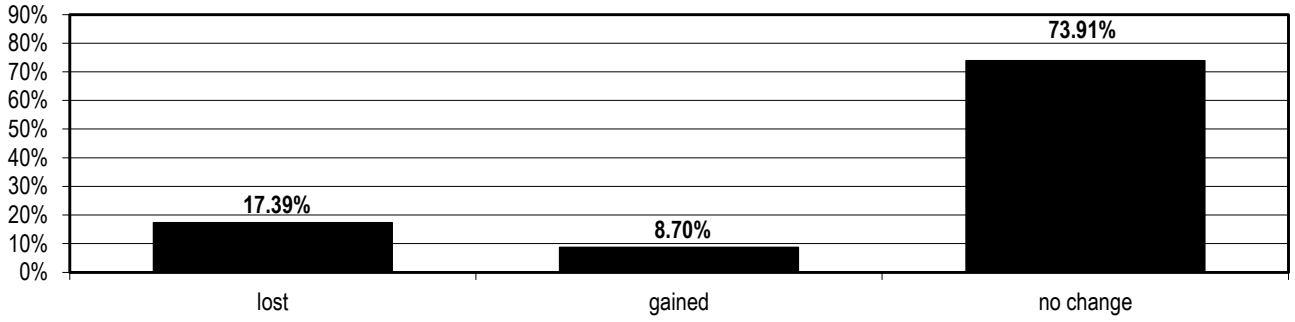
IRB collaborations

2013 saw a rise in the number of IRB collaborations and consortia. These collaborations were formed to streamline multisite review by relying on one central IRB. Experts say 2014 will bring an even greater number of collaborations.

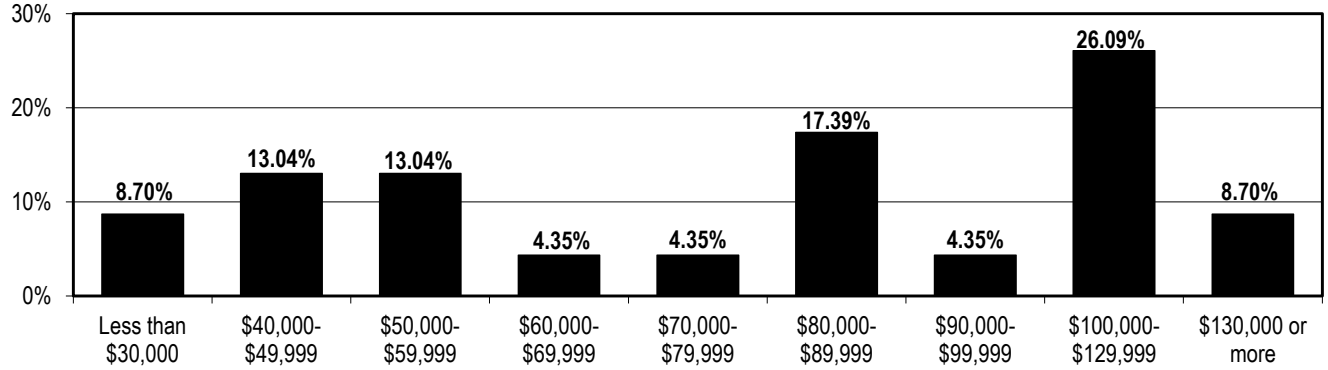
"I think that [the use of central IRBs] is one of the few things that people can predictably expect," says **Mark Schreiner,** MD, chairman of the committee for the protection of human subjects at Children's Hospital of Philadelphia, and a member of the *IRB Advisor* editorial board. "I think that a lot of the NIH [National Institutes of Health] grants are forcing people to agree to use a central IRB. That's pretty clear."

Federal agencies have been pushing for greater use of central IRBs, Schreiner says, as multisite review is expensive, less efficient, and can simply

Has your department lost or gained staff?



What is your annual gross income?



take too long. "There's a lot of concern that it [multisite review] just takes too long, and having multiple reviews doesn't add any value," he adds.

"Some of the literature suggests that IRBs at different sites are asking for different information, and can affect the scientific validity of protocols," Cobb adds. "There's a lot of support for institutions to work together, especially among institutions that received Clinical and Translational Awards."

Some organizations have been reluctant to defer to a central IRB, Cobb says. They may not want to give up institutional control, or have concerns about who will ultimately be responsible if something goes wrong. "There is also reluctance in cases where institutions don't have a relationship," she says. "You want to really be sure of who you're deferring to."

"Another issue is, what are the qualifications to serve as a central IRB?" Schreiner adds. "There are no established criteria to assess whether or not a local IRB is capable of serving as the IRB of record for other IRBs."

Currently, there are no regulatory guidelines for setting up central IRB review. IRBs may be feeling increased pressure as they try to figure out what it means to have that system, and set up the processes for review. Some institutions and funding agencies may not realize how complicated the process can be, Cobb says. "There's a naivete about what is required and that having an IRB authorization agreement is all you need. However, you might have to hire and train someone to handle a central IRB process, or need a new electronic system to track information, or develop new processes for IRB review, and ancillary reviews. There are no rules, so IRBs are inventing as they go along."

IRBs must have more flexibility when deferring to a central IRB, and be willing to accept a decision as long as the proper procedures are followed. "If they do a substantive review and come to different conclusions than we would, that's all right," Schreiner says. "That's part of what you have to agree to if you're going with a central IRB — be willing to say, 'Even if you come to a different conclusion, as long as you went through the right process, we accept you.'"

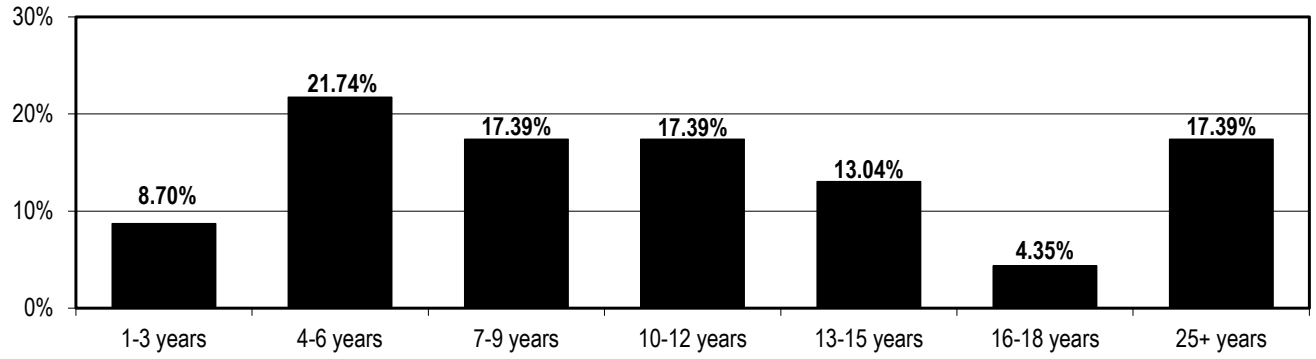
UW-Madison is one institution in the Wisconsin IRB Consortium, a central IRB model consisting of the major research institutions across the state. The model is currently being expanded for use in six more institutions across the Midwest, called the Midwest Area Consortium for Health. "It will work in a more regional than statewide basis," Cobb says. As for WIC, "we're still meeting and tweaking what we're doing," she says. "We reach out to get these relationships going and to sustain them and gently get people to respond to that."

Other survey results

The salary survey also found:

- Most respondents have graduate degrees.
- Nearly half work up to 45 hours per week, and 17% indicated work weeks up to 50 hours.
- Eighty-seven percent of respondents were women.
- Most have worked 4-6 years in the field.
- Thirty-nine percent indicated a 1%-3% increase in salary, and 17% said there was no change. ■

How long have you worked in your present field?



Study: Not all published trial data is complete

Published journal articles of clinical trial results may not give the complete picture of adverse events and other areas, according to a recent study. In addition, only about half of the studies registered to ClinicalTrials.gov were further published in journals.

The US Food and Drug Administration Amendments Act requires that certain clinical trials and research studies involving human subjects be registered on ClinicalTrials.gov, and results published on the website and/or in scientific journals within a year of completion.

To determine the rate of publication and completeness of randomized controlled drug trials, the study authors searched ClinicalTrials.gov for completed drug studies. Of the 600 trials selected, 50% did not have a published journal article. The researchers also found that, of the 202 studies that had a corresponding journal article, reporting was more complete on ClinicalTrials.gov than in published articles in the areas of adverse events (73% vs. 45%, respectively), serious adverse events (99% vs. 63%), efficacy (79% vs. 69%), and flow of participants (64% vs. 48%). Further, the authors found that the median time of study completion to registry publication was 19 months, and journal publication 21 months.[1]

"Our results are important for authors because they point out inconsistencies in reporting and highlight the need for more rigorous adherence to reporting guidelines to ensure that all critical information is provided in study reports," the study authors write in the journal *PLOS Medicine*. "For patients and their clinicians, our results outline the importance of registries to improve transparency in clinical research by making information about clinical trials, including results, publicly available, which is the basis for well-informed decision-making about patients' health."[1]

The authors also state the importance of the study for highlighting publication bias and time-lag bias. "Further, our results highlight the need to assess trial results systematically from both ClinicalTrials.gov and the published article when available," they write. "Based on our results, searching ClinicalTrials.gov is necessary for all published and unpublished trials to obtain more complete data and to identify inconsistencies or discrepancies between the publicly posted results and the publication."[1]

To improve the completeness of trial result reporting, the authors suggest the use of templates for standardized reporting in journals, or broader mandatory registration of results.[1]

REFERENCE

1. Riveros C, Dechartres A, et al. (2013) Timing and Completeness of Trial Results Posted at ClinicalTrials.gov and Published in Journals. *PLoS Med* 10(12): e1001566. doi:10.1371/journal.pmed.1001566 ■

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.

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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

- IRB creates template for conducting QI projects
- Using comics to educate research participants
- Clarifying youth assent in research
- Site focuses on closing inefficiencies leading to delays

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CNE/CME QUESTIONS

1. According to Susie Corl, MSW, MPH, CIP, CCRP, which of the following is a good quality improvement project step?
A. Report suspected systemic problem to leadership
B. Give findings to IRB and leadership
C. IRB implements response and solution
D. All of these are good QI project steps to follow

2. Which of these statements would most clearly ask researchers for information about their chart review study?
A. Describe the inclusion criteria and describe the exclusion criteria
B. Describe the population being studied
C. Describe the medical conditions and medication use that would exclude subjects from your study
D. None of the above

3. Compliance study reviews for an FDA-regulated trial should reference which materials with each observation, according to Sarah White, MPH, CIP?
A. Federal regulations
B. Institutional policy or guidance
C. ICH Good Clinical Practice
D. All of the above

4. According to Nichelle Cobb, PhD, IRB director at University of Wisconsin-Madison, IRBs may be reluctant to defer to a central IRB because:
A. The IRB does not want to give up institutional control.
B. IRBs do not have the time for a collaboration.
C. The institutions do not have an established relationship.
D. Both A and C

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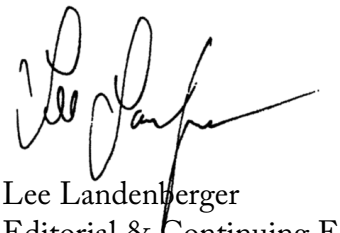

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Editorial & Continuing Education Director