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NOVEMBER 2007
VOL. 7, NO. 11 • (pages 121-132)

Best Practices Update: IRB's quality improvement process identifies concerns and fixes problems

QI department is very well organized

Quality improvement (QI) is such an important part of the daily work process at one independent, Midwestern IRB that there are 17 employees on the regulatory affairs and quality improvement team.

"We have a highly efficient and productive team who keep QI as a top priority," says **Thomas W. Gibson**, RN, BS, director of regulatory affairs and quality improvement at Schulman Associates IRB Inc. of Cincinnati, OH. There are five full-time staff dedicated to quality improvement, Gibson says.

Each year, there is a quality improvement plan and evaluation at Schulman Associates IRB, and these QI reports are presented to the organizational management team with recommendations, Gibson says.

"We have process and outcome indicators for the different teams," he says.

The QI department conducts internal file audits, as well as audits of the web site and IRB meeting minutes each month. "We make sure we have a good representation of all minutes," Gibson explains. "We have an 'opportunities for improvement' database where we look for patterns that could be showing areas of weaknesses."

Gibson and the senior QI coordinator review these at least weekly to make certain they've found every concern that could be made into a QI initiative, he adds.

The QI department produces three different reports each quarter, says **Mary Ellen Kramer**, RN, BSEd, CPHQ, senior quality improvement coordinator for Schulman Associates IRB. One report involves the IRB's data, including information about the IRB's productivity, processes, and volume of work, Kramer adds.

With the QI department in place, the IRB was better able to handle the major change that occurred when investigators began reporting all deviations from the protocol, including thousands of insignificant deviations. The volume of reports handled by the QI department increased

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50-fold between 1999 and this year. **(See story about study deviation reports, p. 123.)**

As an example of the IRB's best practices in quality improvement, here are some of the QI activities the organization has employed:

• **Watch for trends:** By keeping track of the IRB's workload each month, the QI department is able to predict future trends.

IRB Advisor (ISSN 1535-2064) is published monthly by AHC Media LLC, 3525 Piedmont Road, Building Six, Suite 400, Atlanta, GA 30305. Telephone: (404) 262-7436. Periodicals postage paid at Atlanta, GA 30304. POSTMASTER: Send address changes to **IRB Advisor**, P.O. Box 740059, Atlanta, GA 30374.

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Subscription rates: U.S.A., one year (12 issues), $389. Add $12.95 for shipping & handling. Outside U.S., add $30 per year, total prepaid in U.S. funds. Discounts are available for group subscriptions. For pricing information, call Tria Kreutzer at (404) 262-5482. **Back issues**, when available, are $65 each. (GST registration number R128870672.)

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Editorial Questions

Questions or comments?
Call **Paula Cousins** at (816) 237-1833.

For example, if the IRB received an influx of new protocols in October of 2007, then the QI department would expect an increase in continuing reviews in October, 2008, Gibson says.

"The QI employees are all cross-trained with different functions, and they can move to meet the needs of the time when the work becomes heavier," Gibson says.

• **Examine team indicators:** Kramer looks at team indicators to see how the teams are doing, including their volume and turnaround time.

"I look at the experience level of the staff, whether they're hourly or salary employees, and I look at some of the information that is obtained because of requests for proposals or requests for information from sponsors," Kramer says. "Some of the information is specifically important to us, including the turnover rate and retention of staff information, and other information is tracked because of requests from sponsors."

The QI office tracks turnaround time for each area of the office's activities. This includes turnaround time for amendment reviews to turnaround time for full board reviews and expedited reviews, Kramer explains.

"Oftentimes you can break down the turnaround time, starting with the receipt to the organization handling it when it's given to a board member," she adds.

"We look for a bottleneck in the processes to make sure we're timely in turning things around, so we don't hold up a study," Gibson says.

When Kramer first began working for the IRB, the office was tracking turnaround time through paper and pencil monitoring. Now there is electronic tracking, and this makes the process much easier, she says.

"Electronically is the best way, but you can still do it by paper and pencil if you're a small company," Kramer notes.

• **Fixing problems:** "Our goal is to have a less than 6% error rate, but I personally aim for less than 3%," Gibson says. "On my team we stay below the 3%, but I have to take that goal through the whole organization and monitor things closely enough to determine the accuracy or error rate."

Kramer prefers to call it a 97% accuracy rate. "I think it encourages staff to do even better when they see a report on their accuracy rate," she says.

• **Share QI data:** The IRB staff and board are involved in QI processes in a variety of ways. For instance, there is a staff quality improvement

committee that includes representation from the board, management, and IRB staff who see QI data periodically, Kramer says.

Then the entire IRB staff sees QI data during the quality week in which quality improvement is celebrated and promoted from a Sunday to a Saturday.

QI data are posted on cubicle and office walls and in the hallway. It's divided by team and also reflects the board's work.

Since there is so much QI information, each year the QI department selects some specific data to display.

"One year it will be all about team indicators, and another year it will include board information, and another year it will be about QI initiatives," Kramer says. "We try to focus on a certain area of the QI report, which has three different parts."

• **Keep a QI activity summary report:** The QI office has developed a QI activity summary report, using some existing forms and modifying it to suit the IRB office's purposes.

The first page and section of the report asks for a summary of the activity, type, goal, and benchmark. Then there's the question, "How was this identified as a meaningful activity?"

"On the first page we want to list why the activity is meaningful," Kramer says. "It could be that the study has a high volume or is high risk or is problem prone."

Or it could be as simple as one team is using one term to describe a process, and another team is using the same term differently, she notes.

The form has a checklist of processes and other items that need to be checked if they pertain to why the activity is meaningful.

These include submission, pre-review, board, approval, amendment, product safety, recruitment, regulatory affairs, quality improvement, project management, IRB coordinators, document management, information technology, accounting, legal, reception, human resource, and others.

"This form describes the problem," Gibson says. "The whole first part is the activity and why we're doing it and what is the goal."

The second section of the report asks for a summary of measurements, results, analysis, and actions.

"After you've done the measurements for the process and determined the sample size and methodology, then you start doing measurements and put interventions into place, determining how long you want to do this project," Gibson explains.

For example, there could be a new policy put in place and it's measured every six months, using the same methodology to see if the interventions have caused any changes, Gibson says.

There are pages in the QI activity summary for data re-measurements.

The QI activity summary does not need to be applied to all QI issues.

"When we have things that we can resolve in five minutes by switching things around then we don't need to go through this whole process," Gibson says. "This is for major initiatives or issues involving studies that have a high volume or high risk or are prone to problems."

Complicated QI issues also might require the completion of the QI activity summary sheet.

"With the QI activity summary, maybe there are some problems that cross several teams, or these could be a big enough issue that it would need to be a quality improvement study, which is more like a root cause analysis," Kramer says. ■

IRB's deviation reports increase exponentially, leading to process change

QI staff label deviations according to significance

After the FDA in 2000 highlighted the problem of investigators inadequately reporting protocol deviations, sponsors have required all deviations to be reported to the IRB.

This caused the Schulman Associates IRB of Cincinnati, OH, to see an immediate increase in reported protocol deviations from 10-15 per week to 300-450 per week, says **Thomas W. Gibson**, RN, BS, director of regulatory affairs and quality improvement at Schulman Associates IRB Inc. of Cincinnati, OH.

The dramatic increase in reported deviations has continued each year. In 2006, there were 34,000 deviations reported. This year, the IRB anticipates having close to 40,000 reported deviations, Gibson says.

Another factor contributing to the increase in reported deviations is that the IRB's own business has increased, notes **Mary Ellen Kramer**, RN, BSEd, CPHQ, senior quality improvement coordinator for Schulman Associates IRB.

"These are challenges that you have to manage all of the time," Kramer says. "You think you've fixed it, and then another issue comes up."

So any QI process created to handle this issue would need to be ongoing, Kramer adds.

"As this number increased we had to do a QI initiative because sponsors were telling all their sites to report everything, whereas the regulations say you only need to report significant deviations in a protocol," Gibson says. "As a result, we had to develop a classification system."

The system divides the reported deviations between those that are significant and must be reported and those that do not need to be reported. The number of reports is too large to take all of them to the IRB, so some kind of triage needs to be performed.

The first step was to look at the study populations involved and to develop a way to classify the reported deviations, Gibson recalls.

For example, if a deviation stated that the study participant was stuck in traffic and, as a result, received the study drug five minutes later than the window allowed, this likely would be an insignificant deviation, he says.

However, if an investigator's computer hard drive, containing confidential study participant information, was stolen, then that needs to be reported and would be classified as a significant deviation, Gibson says.

Also, context matters. If an investigator made an error during the informed consent process, but it was the first time this occurred, and the investigator also filed information about the measures he or she took to correct the problem, then it would be reported to the board, but as an attachment that doesn't require discussion, Gibson explains.

The same incident would become a compliance issue and taken to the full board for discussion if it was the second or third time that the investigator made a mistake in providing informed consent to participants, Gibson adds.

The QI department has whittled down the reported deviations to 3,000-4,000 significant deviations per year that the IRB has to discuss, Gibson says.

The board is notified of many more than that number, but these are not issues of noncompliance and do not need to be discussed, he adds.

Deviations first are entered into the database by three administrator assistants. After that they are handled by a senior compliance coordinator and staff who review them and classify them as insignificant or significant and in need of follow-up, Gibson says.

"About 20% of the deviations require follow-up because they haven't submitted the necessary information to help us understand what's going on," he says. "Or they don't have adequate measures in place to prevent the deviation from happening again."

Deviations labeled as "significant" are put on the IRB's agenda. If the deviation is both significant and a noncompliance issue, then Gibson and the senior compliance coordinator will go to a pre-board meeting on Tuesday morning and meet with several legal representatives, board members, and the IRB chair to discuss these particular deviations and noncompliance issues, he explains.

"At that time they decide whether they want the deviation to go to the board on a Wednesday or Friday meeting, or they say they would like to know more information," Gibson says.

Once this process is done, the senior compliance coordinator will make sure each deviation reviewed is marked as "no action needed," or however it has been handled, and then they're sent back to the investigators for their files.

To make certain QI professionals have accurately identified the significant versus insignificant deviations, there is an ongoing inter-rater reliability check conducted. Several IRB members who are physicians will conduct quality checks on a random number of reported deviations and make their own judgments about whether these are significant and issues that need to be reported to the full board. Their assessments are compared with the staff's assessments, and typically the two are the same, Gibson says. ■

Institution's QI form serves as educational tool for PIs

It helps in identifying strengths, weaknesses

Education is the foundation of quality improvement, which is why one IRB's main educational tool for investigators is an on-line form for quality improvement through self-assessment.

"We want to help investigators identify strengths and weaknesses in their own systems, and we want to help them understand how to fix it," says **Judi Kuhl**, BS, CIP, quality improvement

program coordinator in the office of research integrity at the University of Kentucky in Lexington, KY.

"We looked at a lot of different models, and we came up with an educational approach," Kuhl says. "We thought that was the best thing to keep a good rapport and to keep the focus on quality improvement instead of a punitive approach."

The IRB has the authority to require that an investigator complete this form if necessary, but that's not the form's primary focus, she adds.

With help from consultants, Kuhl refined a less comprehensive QI form after she joined the office of research integrity in 2003.

Before launching the tool system-wide, the institution piloted it among several investigators and experts outside of the university, Kuhl says.

"The feedback I got was it was very, very thorough, and it seemed comprehensive in terms of what investigators need to be doing," she says.

Investigators can use the tool to see what mechanisms are in place to protect human subjects and how they can fix problems within their own systems, Kuhl says.

The self-assessment tool is completed entirely on-line, and there's a sample completed form that investigators can use as a reference.

Under its menu, there are 10 sections to complete. They are as follows:

• **Regulatory documents:** "If it's an FDA-regulated study, they have questions to answer pertaining to that," Kuhl explains.

• **IRB documentation:** These questions are about how well the investigator is maintaining records for IRB correspondence. These include both institutional policy and regulatory issues, she explains.

• **Subject recruitment procedures:** The idea here is to make certain the investigator is following any recruitment methods approved by the IRB.

• **Unanticipated problems/adverse event reporting:** "This section gets into whether they've submitted everything they're supposed to submit to the IRB," Kuhl says.

• **Drug/device accountability:** "We have an investigational drug service [IDS] at our university, and that operates through our pharmacy where they handle all research drugs," Kuhl explains. "The questions cater to those individuals who do not use the investigational drug service because the IDS does a lot of accountability type control things."

• **Record keeping:** Questions pertain to how long the investigator maintains files.

• **Other compliance categories:** There are a number of committees to which a principal investigator will have to submit forms, so this section covers the other submissions, including those to the institutional biosafety committee, the general clinical research center, the radioactive drug research committee, the radiation safety committee, and the cancer center's committee, Kuhl says.

• **Informed consent categories:** Investigators will answer questions about how they are conducting the informed consent process and whether they have a signed consent form on file for subjects. The form also requests the investigator list dates when a sample of consent forms were signed and the date when the IRB approved the consent form document.

• **Individual subject review:** Questions here include these: Did any research procedures commence prior to IRB approval, and is there an inclusion/exclusion criteria checklist?

• **Case report form/source documents:** "These questions include: Are there source documents? Do you have case report forms? Are the data in source documents matching what you have in the case report forms?" Kuhl says.

Kuhl frequently shares the form, which was developed with funds from the National Institutes of Health with other institutions and IRB professionals.

"I get e-mails regularly, and I send them the completed version," Kuhl says. "They need only to get into the web page and enter a password that I've given them."

University of Kentucky investigators also use the sample completed form this way, and this is one way that it serves as an educational tool, she notes.

When investigators instead use the form as a QI tool, they answer questions electronically and save the data into a database that Kuhl can access.

"They can save each section's information as they work on it," she says. "I don't analyze the data until they've submitted the form as completed."

Investigators also can retrieve their existing form's answers and change these if they need to.

When an investigator's answer indicates a compliance problem, the system will automatically send the investigator a corrective action suggestion.

"Corrective actions are automatic," Kuhl says.

"The answer they give is what triggers whether or not a corrective action will show up."

Once an investigator makes the correction, he or she can change the answer.

"When they feel like they are done with the form, they hit the button that says it's completed, and all of the data goes into a database where I can look at it and analyze it," Kuhl says.

"In analyzing the data, I wouldn't necessarily bring a problem to the IRB as a QI issue unless I saw something that was significantly deficient," Kuhl says. "For example, if the investigator had not obtained consent from any of his subjects, then that would be an example of a major deficiency."

Most of the answers are requested in a "yes," "no," or "N/A" (not applicable) format.

Here are some sample questions regarding the IRB process and the corrective actions when the answer demonstrates noncompliance:

• **Is all correspondence (e.g., e-mails, submissions) to and from the IRB on file?**

Corrective Action: Obtain/retrieve all research-related correspondence to and from the IRB that may be missing from your records. You may contact the Office of Research Integrity for comparison with their IRB records.

• **Is the initial IRB approval letter on file?**

Corrective Action: Obtain/retrieve the initial approval letter issued by the IRB, or request a duplicate from the Office of Research Integrity, and place a note in your records explaining the letter copy.

• **If subjects withdrew from the study, was an explanation for each withdrawal submitted to the IRB?**

Corrective Action: Report to the IRB in writing how many subjects have withdrawn from the study (i.e., could not follow the process, PI terminated their participation) and explain why they withdrew. If the subject withdrawal was due to an adverse event or unanticipated problem, it may be necessary to also submit an UK/VA Adverse Event/Unanticipated Problem Form to the IRB if one has not already been submitted.

• **Is the most recently approved list of key personnel still accurate?**

Corrective Action: Submit in writing to the IRB a current list of all key personnel holding responsibilities with the study, using the format provided to the key personnel section of the General Information Sheet (in IRB application). Include a cover memo describing who is being added or removed.

At the end of each section there is a field in which the principal investigator can enter explanations or comments about any information they've provided, Kuhl says.

"We thought that was necessary because we understand that in reality not everything is a 'yes' or 'no,'" Kuhl says. "So we wanted to give them a chance to explain something if they needed to."

The next step for Kuhl's office is to update the tool, a process that's underway now.

"Because our institution has gone through the accreditation process, we have a lot of things that have changed policy-wise and document-wise, and there are a lot of references in the tool where the documents no longer exist or have moved," Kuhl explains. "So I'm in the middle of updating it regarding that."

As she updates, Kuhl is making certain the answers still are relevant to current regulations.

"That's why the form was very time consuming to develop," Kuhl says. "It wasn't just asking a question and getting a 'yes' or 'no' answer; we went a step further and got all kinds of information about why we're asking that question, and that includes federal information and references." ■

Reporting results from biomonitoring studies

What should subjects be told about exposures?

Biomonitoring—measuring levels of environmental toxins in biological samples taken from volunteers—is an important tool in public health research, providing valuable information about local exposure levels.

Some biomonitoring researchers seek to go further, including a mechanism for reporting back to participants about their individual "body burdens" (the level of contaminants in their own blood, urine, or breast milk, or in their homes). They say participants have a right to know the information, so that they can take steps, if possible, to reduce their exposure.

But this approach comes with some potentially sticky questions for researchers and IRBs. How should this information be communicated? What should participants be told, particularly about environmental exposures researchers don't fully understand yet? And how much control should

IRBs exert over the individual process of communicating with participants?

Julia Green Brody, PhD, executive director of the Silent Spring Institute, Newton, MA, says that when her group studied levels of endocrine-disrupting compounds in homes and individuals in Massachusetts and California, they soon decided they should report individual results to participants.

"Our core values led us to really value the relationship between the scientific team and the community where we're doing our research," she says.

At the same time, Brody says this was a very new area of science, noting that of the 89 compounds for which participants and their homes were tested, 30 had never been looked at in an indoor environment before.

"There wasn't any off-the-shelf package for how to do this," she says. "So our team really began engaging in discussion about what was the best approach."

Researchers went to the community that was assisting in the study—residents in Cape Cod, MA, and later in Richmond, CA, as well as members of the Massachusetts Breast Cancer Coalition and the California-based Citizens for a Better Environment (CBE)—to help shape the report-back plan.

Green says community leaders strongly urged reporting back to individuals, even for contaminants about which little is known.

Phil Brown, PhD, a professor of sociology and environmental studies at Brown University, and **Rachel Morello-Frosch**, PhD, MPH, an assistant professor of environmental health at the University of California, Berkeley, shepherded the research collaborative's biomonitoring project through the Brown University IRB.[1]

Brown says that the biggest initial concern raised by the IRB regarded the involvement of the Silent Spring Institute and Communities for a Better Environment—two independent entities whom board members feared they would not be able to adequately oversee.

"An IRB can discipline its own researchers on campus," Brown says. "They didn't have any knowledge of how they could influence or control a community organization that is not part of Brown University."

Brown says his group was able to convince the IRB that Silent Spring had an extensive record of research, much of it federally funded, and that CBE was an established environmental activist group, with its own legal team. Everyone involved in the project was willing to take required human subjects protection courses, and Brown University's co-PIs would conduct checks of the organizations' recordkeeping and data storage procedures.

Brown pointed out that these types of community/institutional partnerships are becoming more common.

"We spent a lot of time detailing how widespread this new practice was, why it was important and why it would be worthwhile for them to cover it," he says. "The National Institutes of Health is the main funding source for a lot of these new partnerships, in particular the National Institute of Environmental Health Sciences."

Opportunities for taking action

In the end, the Brown University IRB agreed to cover the organizations and had few problems with the proposed protocol itself, including the report-back procedures.

Individual reports were to be presented in a graphic format, showing a participant how the household's information compared not only to EPA health guidelines, but to other homes in the study.

The charts would be accompanied by verbal summaries that distilled the key messages. Participants were told as much as researchers knew about the possible sources of the contamination, so they could take steps to reduce exposure.

"That's part of the importance of reporting—to give people the opportunity to do that," Brody says. "It makes it possible for people to take action and helps people understand why they might want to take action."

Phil Brown says the Brown IRB did emphasize that any meetings called to report back to the community shouldn't consist entirely of individuals who had contributed data. The board's concern was that an individual attending that meeting could look around and know who the other study participants were.

"We should be clear that we were sending invitations to a wide range of people who lived in the area," he says. "Some of them might be involved in the study, but there was no way anybody could know they were involved."

Brown says the collaborative had far more problems with the Massachusetts Department of Public Health's Research and Data Access Review Committee (RaDAR), which had to

approve the study because it involved subjects originally drawn from the Massachusetts Cancer Registry, a government-held database.

That committee raised several concerns about the project, including the researchers' plans to provide individual reports to subjects.

"At some point, they wanted us to show them every single letter that would have gone out (to participants)," Brown says, noting that would have required the committees' approval of about 120 letters. Eventually, the committee agreed to review only a template of the letter.

The RaDAR committee also originally called for the destruction of environmental and biological samples immediately after the first chemical analyses were completed. Eventually, the committee withdrew that requirement as well, as long as the research team obtained a new consent form from the participants allowing further storage of the samples.

Brown says destroying the samples would have been devastating to future research. As an example, he points to a recent study showing that childhood exposure to the now-banned pesticide DDT was associated with breast cancer later in life.

"The researchers had discovered an incredible databank of blood samples from decades ago," Brown says. "If those samples had been destroyed, this major scientific advance would not be possible.

"We know, day to day, how much science advances," he says. "Things are developing so quickly that we owe it to people to keep samples as long as they can be protected, so we can analyze this kind of data."

Brown says IRB approval of this study was eased by the fact that the researchers did not attempt to engage participants in publicly announcing the results of their biomonitoring, as other projects have done.

In one case, an environmental group put individual results on a web site (with participants' permission), to put a human face on the problem of environmental contamination.

Brown believes that IRBs should be willing to approve research designs that include such public disclosure, as long as the informed consent makes it clear that participants can decline to reveal their own data.

"I would hope that an IRB confronted with that would say, 'Yes, people should have that right,'" Brown says. "It's a basic right of your own data."

Clarity, follow-up important

Brody and Brown say IRBs should consider several other issues in reviewing biomonitoring studies.

- **Choice:** Brody says the informed consent process should spell out that participants have the option either to receive their individual results or to decline them.
- **Clarity:** In looking at a template of the individual reports, Brody says the IRB member should be sure the information is complete, but understandable.

"Which doesn't mean dumb it down—that is key," she says. "I think there's been a kind of knee-jerk reaction that people can't understand rich scientific information and our experience has been very consistent that people want to be told in quite a bit of detail."

In particular, she says, the report should be very clear about what is and isn't known.

"You need to be cautious about making unsubstantiated recommendations, or providing unsubstantiated reassurance," she says.

- **Potential follow-up:** Brody says the team's experience in writing the summaries has been that giving participants an understanding of both the results and what they may mean requires a broad and deep knowledge of the science.

To help with any questions, participants receiving reports were given the phone number of the study's chief toxicologist, who read all of the individual summaries. Brody says a few participants did end up calling her.

They also were encouraged to speak with prominent community-based participants, for example a breast cancer survivor who was active in the Massachusetts Breast Cancer Coalition.

"She is very well known in the Cape Cod community," Brody says. "And she did speak to many study participants after they got their study results."

- **Risks of affecting behavior:** Brown says concerns about the effects of biomonitoring on people's subsequent behavior may be overstated.

In particular, there has been concern that studies revealing the presence of chemicals in breast milk samples might lead women to stop breastfeeding their children.

"All of the studies that have looked at this have been very careful to say that the evidence is overwhelming that the benefits of breastfeeding are much greater than the risks and we encourage people to breastfeed," Brown says. "In research around that, we've found that people do

continue to breastfeed, that testing breast milk has not scared them away."

• **Community representation:** Brown says IRBs should include members who can provide perspective from the community being studied. This can help avoid "helicopter research," in which researchers swoop in and conduct studies without giving results back to the community or providing them any benefit of the knowledge gained, Brown says.

He suggests paying community members to serve on an IRB, if necessary. He says the NIH could pilot a program in which a small percentage of grants at major research institutions are set aside to pay community members for their participation.

"After a few years, look at how this affected the way the IRB operated—were there new policies as a result? Did professionals at the university learn from the community representative? Were there better protections for the community than before?" ■

Reference

1. Brody JG, Morello-Frosch R, Brown P, et al. Improving disclosure and consent: "Is it safe?" New ethics for reporting personal exposures to environmental chemicals. *Am J Public Health* 2007;97:1547-1554.

Decision aids in clinical trials can enhance informed consent

Tools help match decisions to subjects' values

As research participants confront ever more-complicated clinical trials, they also encounter longer, more complex consent forms. Concerns that informed consent isn't necessarily enhanced by these documents has led researchers to seek more useful ways of educating subjects about the study they're considering.

One alternative, the decision aid (DA), uses graphic representations and worksheets to explain a study in a user-friendly way, and to help guide a potential subject to an informed decision about whether to participate.

In recent years, studies have revealed a tension between disclosing all necessary information to study participants and making that information understandable, says **Jamie Brehaut**, PhD, a scientist in clinical epidemiology at the Ottawa Health Research Institute in Canada, and associate director of the Ottawa Patient Decision Support Laboratory.

"Anybody who's on an IRB will likely have experienced the feeling that the consent materials these days are getting more complicated," Brehaut says. "They're getting longer and more detailed. Along with that though is the realization now that sometimes people who are participating in trials don't understand even some of the basic tenets of what they're participating in."

While there have been initiatives to improve the readability of consent documents and to make their formats more user-friendly, Brehaut says it's time to move beyond those efforts at creating what he calls "barely informed consent."

"We need to think about good decision making," he says. "That's what I think the goal should be when we're talking about helping a person decide whether to participate in a clinical trial."

Proponents of decision aids say they do a better job of outlining not just the particulars of a study, but what values are important to an individual participant weighing whether to sign up. They also describe other options, such as the standard care or no treatment at all, that participants could choose instead.

"Clinical trial consent forms traditionally present comprehensive information only about the clinical trial in consideration," says **Ilona Juraskova**, PhD, a senior post-doctoral researcher in the Medical Psychology Research Unit at the University of Sydney in Australia.

"In contrast, the DAs present all options available for the patient/consumer, including the status quo, and make the reasons for and against trial participation explicit. Furthermore, risk information is presented in numerical, graphical, and visual formats, which have been proven to be the most easily understood and integrated into decision making."

She says decision aids could be particularly useful in more complicated studies.

"The more complex the decision, the more useful a DA will be," she says. "For complex trials with many treatment arms, or where there are large potential costs of participation, DAs may be particularly helpful."

'Preference-sensitive decisions'

Decision aids have been used for years to help patients decide on a course of treatment in

situations with several possible options, depending on the preferences of the patient.

"It's for those what we call preference-sensitive decisions that patient treatment decision aids were developed," Brehaut says. "What they do is they improve decision making under situations when there's no obviously correct answer."

Brehaut says that there are three key points to a good medical decision that can be addressed by decision aids:

- an understanding of the key aspects of the decision;
- an accurate idea of what the probabilities of the different outcomes are;
- finding a match between the choice being made and the kind of outcome the patient thinks is most important.

Aid used in breast cancer study includes graphics, worksheets

Options shown to potential participants

Elements in the decision aids created for the IBIS-II breast cancer study:

- a layman's explanation of the concept of "breast cancer risk" and factors that contribute to an increased risk of breast cancer;
- numerical and graphical representations of breast cancer risks for the general population;
- diagrams of risk management options—standard care versus clinical trial, along with pros and cons of each;
- lay descriptions of the drug anastrozole, its physical properties, risks and benefits, and a graphic illustration of its effectiveness and side effects;
- similar descriptions and graphic illustrations for tamoxifen, the standard treatment option in the trial;
- the rationale for conducting clinical trials in general and IBIS-II in particular, along with descriptions of key terms such as randomization and placebo; and
- personalized worksheets of value clarification exercises, which help women evaluate the various risks and benefits to see which are most important to them. ■

"(The aid) can have exercises to make explicit to people the outcomes that they're interested in, as individuals" Brehaut says. "Which outcomes do you particularly value?"

The tools themselves can be paper-based, often in a workbook format, or on-line exercises. They're usually not a shorter, simpler version of an informed consent document—in fact, Brehaut says, it's intended that the patient will spend some time with a decision aid.

"It's not going to result in a lot of time savings in terms of arriving at the decision," he says. "What it does do is it helps people make better use of their time. So rather than working through a complex (informed consent) document that doesn't provide you any help to work through it, the decision aid has the potential to allow people to make good use of their time."

While research has shown that patients using decision aids have increased knowledge about and satisfaction with their medical decisions, Brehaut says there has been relatively little research done on the possible benefits of using DAs to help people decide whether to enroll in a clinical trial.

To get at that question, Juraskova and her team, which includes professors Phyllis Butow and John F. Forbes, have developed a decision aid for use in the International Breast Cancer Intervention Study II (IBIS-II), a multicenter, randomized clinical trial being conducted in the United Kingdom, Australia, and New Zealand. The trial is investigating the use of anastrozole by postmenopausal women at increased risk of breast cancer.

Juraskova's team created decision aids to help women decide whether to sign up for IBIS-II.

The aids included explanations of all the possible options available to women in the trial, including the standard care and the study drug. It also explained the concepts and terms involved in clinical trials and provided worksheets to help women work through their own preferences.

Graphic representations help take abstract ideas like risk and put them into a context for potential subjects. A page might show a field of dots, with the percentage of people who might experience certain side effects shaded in. "Balance scales" help rate perception of risks and benefits to "weigh" a decision. The aids include examples of worksheets filled out by hypothetical subjects, one showing a subject leaning toward participation, one leaning against enrolling.

In designing the DA booklets, Juraskova's team reviewed findings from studies in which cancer patients described questions they would ask about clinical trial participation and how they would like to see information presented.

Juraskova's team tested the decision aids among women who had already participated in an earlier version of IBIS, to judge their use in addition to a standard informed consent document.

A substantial majority (87%) found the DA helpful in understanding the informed consent document and 90% preferred receiving both documents to the informed consent document alone.

Respondents said that not only was the decision aid easier to understand, but that it would make a good reference once a person had enrolled in the trial, Juraskova says.

International standards

Brehaut predicts that similar studies will explore the usefulness of decision aids in clinical trial decision making, as part of the larger effort to improve informed consent in research.

"I think there is an understanding out there that informed consent process needs to be improved and the decision aid approach seems to be potentially a fruitful way to look at it," he says.

An IRB confronted with a decision aid in a clinical trial should check to be sure that it has been created according to criteria set by the International Patient Decision Aids Standards Collaboration (www.ipdas.ohri.ca).

"This represents an international consensus on best practice," Juraskova says.

Brehaut says the effectiveness of a decision aid should be measured by indications of good decision making, not just whether the document is readable, or whether subjects can recite facts about the trial.

"Does the decision aid have a specific exercise for determining what outcomes a patient particularly values?" he asks. "Which are the outcomes they particularly want to avoid, which are the ones that they are particularly interested in?

"If you're testing if a decision aid works or not, there should be some sort of measure for understanding whether the decision aid process increases the match between the outcomes that they value and the thing they ultimately choose."

Juraskova notes that proposed studies using decision aids also should outline realistic ways of implementing them. DAs do involve a time

CE/CME *questions*

17. When conducting a quality improvement process to reduce the number of protocol deviations reported to an IRB, which of the following is a good first step to take?
    A. Look at the study populations involved and develop a way to divide reported deviations between those that are significant and needing to be reported and those that are insignificant and do not need to be reported.
    B. Send all reported deviations involving high-risk trials to the IRB for review, and discard all of those involving low- or medium-risk trials.
    C. Form a committee to look at protocol deviations.
    D. None of the above

18. Which of the following would be a good category to include in a quality improvement self-assessment tool for principal investigators?
    A. IRB documentation
    B. Subject recruitment procedures
    C. Unanticipated problems/adverse event reporting
    D. All of the above

19. What is a body burden?
    A. The difficulty experienced by a single research volunteer during the course of a research study
    B. The potential risk to a study participant in a biomonitoring study
    C. The level of environmental contaminants in a person's blood, urine, or breast milk, or in the home
    D. None of the above

20. The use of a decision aid in informed consent can greatly speed up the process.
    A. True
    B. False

Answers: 17. (a); 18. (d); 19. (c); 20. (b)

COMING IN FUTURE MONTHS

- Improve communication between IRB and other committees
- Follow these tips to educate community about human subjects protection
- Rare disease research can come with special challenges for IRBs
- Setting up IRBs in developing countries

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commitment, especially more complex ones, which are accompanied by a video or are computer-based.

She says that costs of creating a decision aid may be prohibitive in smaller trials, but her group hopes to create a template based on their work with IBIS-II that might help make the development of other DAs easier and less expensive. ■

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Statement of Ownership

United States Postal Service
Statement of Ownership, Management, and Circulation

1. Publication Title	2. Publication No.	3. Filing Date
IRB Advisor	1 5 3 5 - 2 0 6 4	10/1/07
4. Issue Frequency	5. Number of Issues Published Annually	6. Annual Subscription Price
Monthly	12	$389.00

7. Complete Mailing Address of Known Office of Publication *(Not Printer) (Street, city, county, state, and ZIP+4)*
3525 Piedmont Road, Bldg. 6, Ste. 400, Atlanta, Fulton County, GA 30305

Contact Person: Robin Salet
Telephone: 404/262-5489

8. Complete Mailing Address of Headquarters or General Business Office of Publisher *(Not Printer)*
3525 Piedmont Road, Bldg. 6, Ste. 400, Atlanta, GA 30305

9. Full Names and Complete Mailing Addresses of Publisher, Editor, and Managing Editor *(Do Not Leave Blank)*

Publisher *(Name and Complete Mailing Address)*
Brenda Mooney, 3525 Piedmont Road, Bldg. 6, Ste. 400, Atlanta, GA 30305

Editor *(Name and Complete Mailing Address)*
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Full Name	Complete Mailing Address
Thompson Publishing Group Inc.	1725 K Street NW, Suite 700
	Washington, D.C. 20006

12. Tax Status *(For completion by nonprofit organizations authorized to mail at nonprofit rates.) (Check one)*
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☐ Has Not Changed During Preceding 12 Months
☐ Has Changed During Preceding 12 Months *(Publisher must submit explanation of change with this statement)*

PS Form **3526**, September 1998 *See instructions on Reverse)*

13. Publication Name: IRB Advisor
14. Issue Date for Circulation Data Below: September 2007

15. Extent and Nature of Circulation			Average No. of Copies Each Issue During Preceding 12 Months	Actual No. Copies of Single Issue Published Nearest to Filing Date
a. Total No. Copies *(Net Press Run)*			1387	1318
b. Paid and/or Requested Circulation	(1)	Paid/Requested Outside-County Mail Subscriptions Stated on Form 3541. *(Include advertiser's proof and exchange copies)*	609	589
	(2)	Paid In-County Subscriptions *(Include advertiser's proof and exchange copies)*	5	5
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c. Total Paid and/or Requested Circulation *(Sum of 15b(1) and 15b(2)*			1020	1006
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h. Copies Not Distributed			327	272
i. Total *(Sum of 15g, and h.*			1387	1318
Percent Paid and/or Requested Circulation *(15c divided by 15g times 100)*			96%	96%

16. Publication of Statement of Ownership
Publication required. Will be printed in the November 2007 issue of this publication. ☐ Publication not required.

17. Signature and Title of Editor, Publisher, Business Manager, or Owner: Brenda L. Mooney Publisher — Date: 9/27/07

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IRB ADVISOR
Your Practical Guide To Institutional Review Board Management

Good IRB professionals are hard to find

Institutions increasingly looking for advanced degrees

Experienced and educated IRB professionals are in a very good position this year to command top salaries and find jobs in a variety of research settings, according to experts and the results of the 2007 salary survey conducted by *IRB Advisor*.

"What's happening nationally is those institutions that value their IRBs or human subjects protections programs really hang on to their people and throw money at them," says **Barbara J. LoDico**, BS, CIP, director of human subjects research at The Children's Hospital of Philadelphia in Philadelphia, PA.

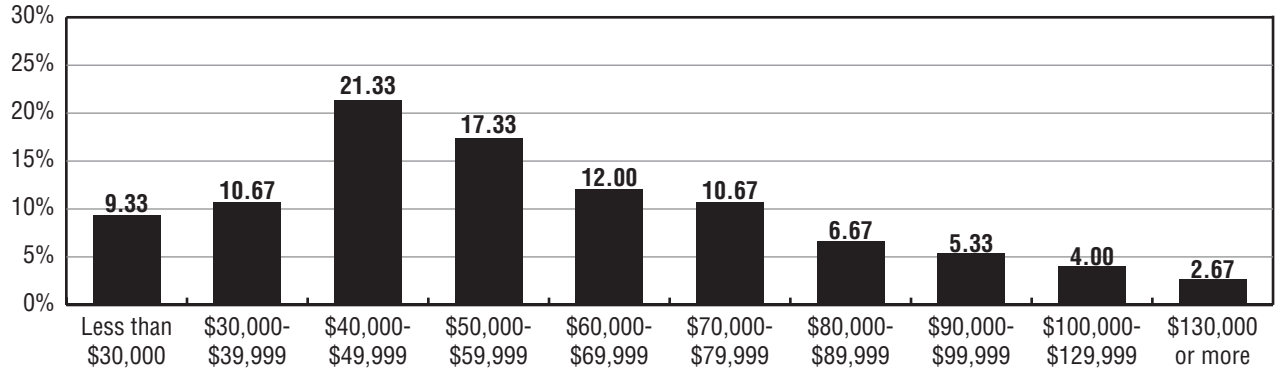
Based on 75 responses to the *IRB Advisor's* 2007 salary survey, most IRB directors and staff who responded earn more than $40,000 a year. Nearly 60% earn more than $50,000 per year, and more than half earn more than $60,000 per year. **(See salary chart, below.)**

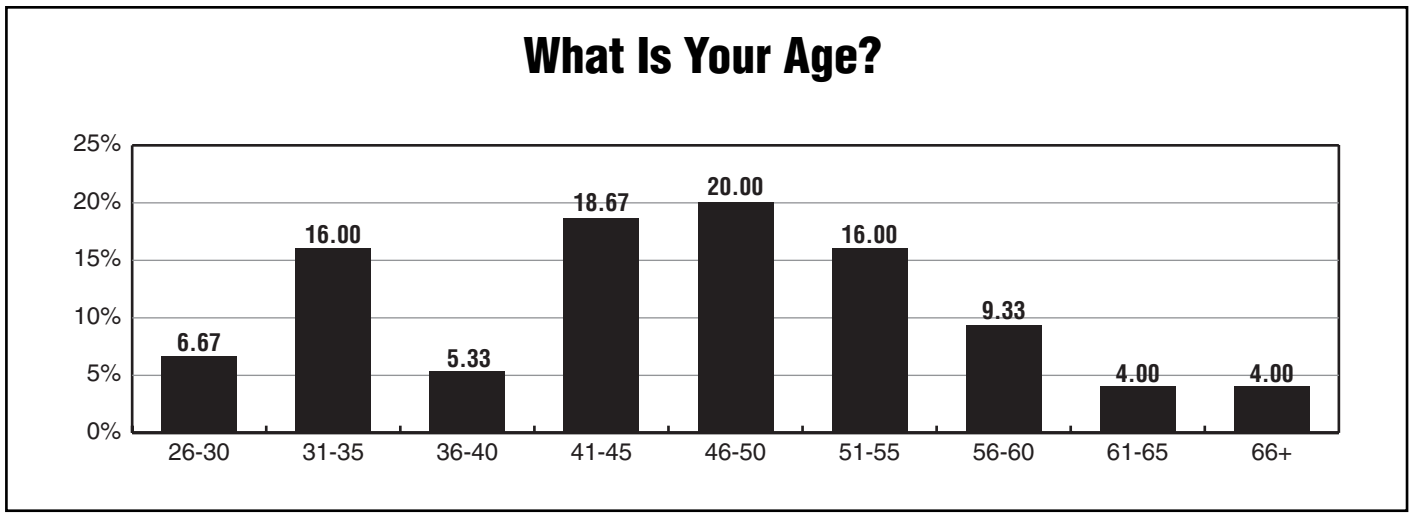
"I've tried to recruit people who the minute they talk to their institution and say, 'I'll give you my notice of 60 days,' the employer says, 'Wait a minute, will this be a matter of compensation?'" LoDico says.

The salary survey also found that close to 83% of respondents received a raise in the past year, with 46.67% earning a 1-3% salary increase, and 20% earning a 4-6% salary increase.

It's very difficult to find qualified people, says **John Isidor**, JD, chief executive officer of Schulman Associates IRB in Cincinnati, OH. Isidor is an editorial advisory board member of *IRB Advisor*.

What Is Your Annual Gross Income?





"We use a company that contacts people at other institutions and will charge some sort of placement fee," Isidor says. "We also market through our web site, and I think a fair number of people look at that."

Schulman Associates runs help wanted ads in the local newspaper, and these have a wider stretch because the newspaper places them on the Internet, he adds.

Seasoned professionals

The 2007 salary survey also noted that the IRB world is attracting older professionals. According to the survey, about 70% of survey respondents are 41 years or older, and more than half are 46 years and older. **(See age chart, above.)**

It's a graying business, Isidor notes.

"I think a lot of people who got into the business in the 1980s and early 1990s have stayed in it," Isidor says. "When they got into it, the IRB world was extraordinarily young, and this was particularly true in the 1980s."

While there is a core of younger people in the IRB world, the fact is that younger IRB professionals tend to be recruited to different types of jobs, Isidor says.

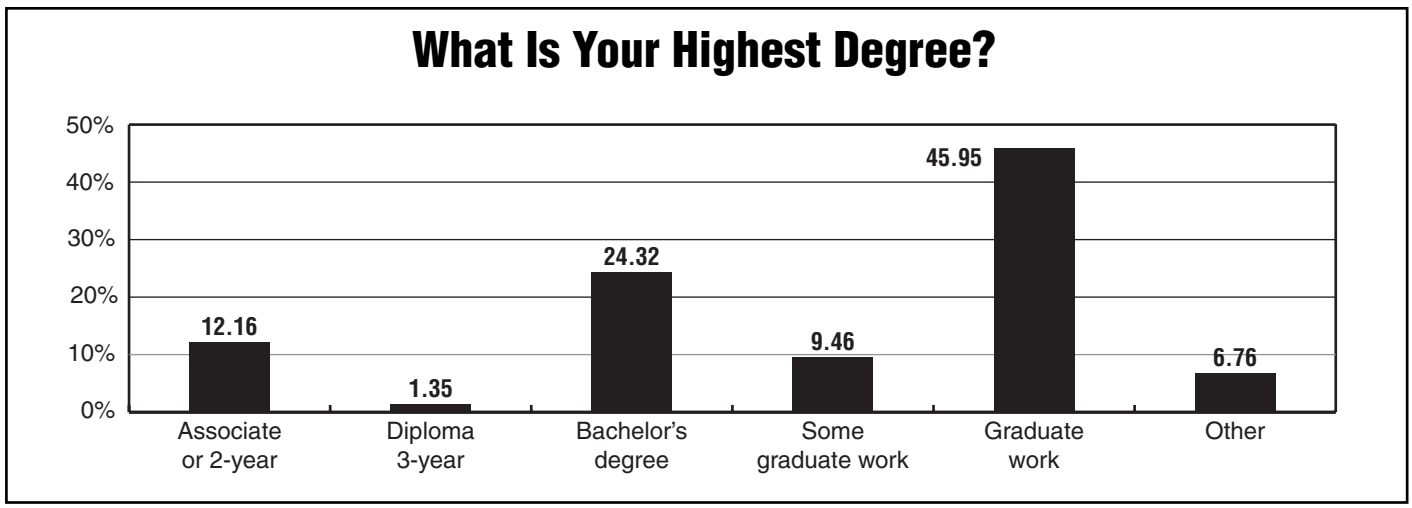
"We've lost a lot of our younger staff to sponsors and contract research organizations, who cherry-pick them," Isidor says.

At the same time, it's difficult to recruit people with experience, even when an IRB has a good reputation and pays competitive salaries, Isidor says.

Research-specific curricula needed

IRBs and institutions that need to recruit new IRB professionals likely would benefit from having universities create courses that focus on education for IRB staff, says **Elizabeth E. Hill**, RN, DNSc, a nurse planner, an assistant professor, and the director of the clinical research management program for Duke University School of Nursing in Durham, NC. Hill also is on the editorial advisory board for *IRB Advisor*.

"There's no school that gives you a degree in IRB administration, and it's not part of any health



sciences program," LoDico says.

"I do think it would be a good idea to have some kind of education for people who run and manage IRBs," Hill adds.

"I ran an IRB in the military for five years, and the people who worked on it had no education—they learned by the seat of their pants," Hill says. "But especially now as we see more about certification and how that's becoming more important, I think these people need to have a good understanding of what is needed in a consent form, and more."

Isidor says he's never recruited new employees at colleges.

"What we try to find are people who have been study coordinators, people who have worked at clinical research organizations (CROs), or sponsors," Isidor says. "And we have a young man who has a master's degree in bioethics from Penn, and he sought us out."

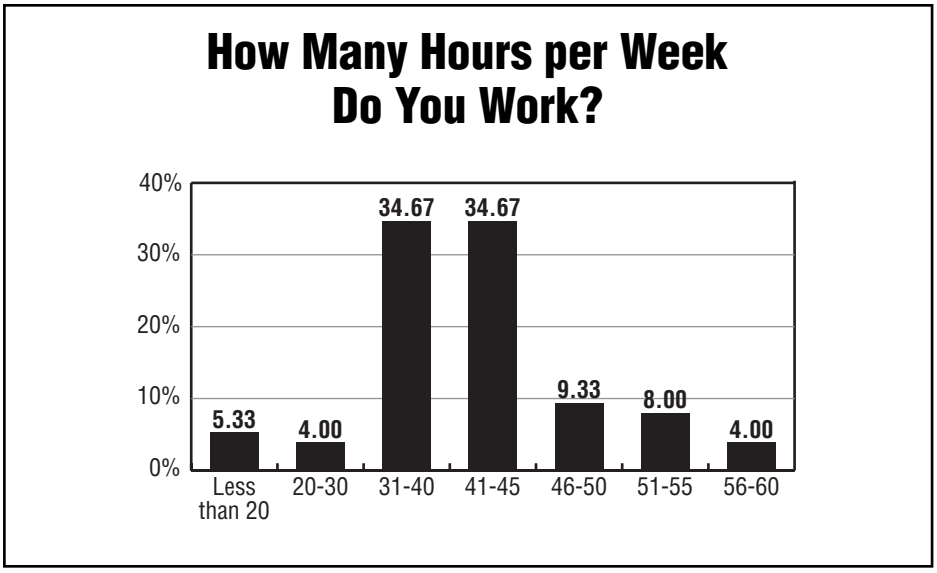
Sometimes potential employees have requested to do an internship at the IRB, as well, he adds.

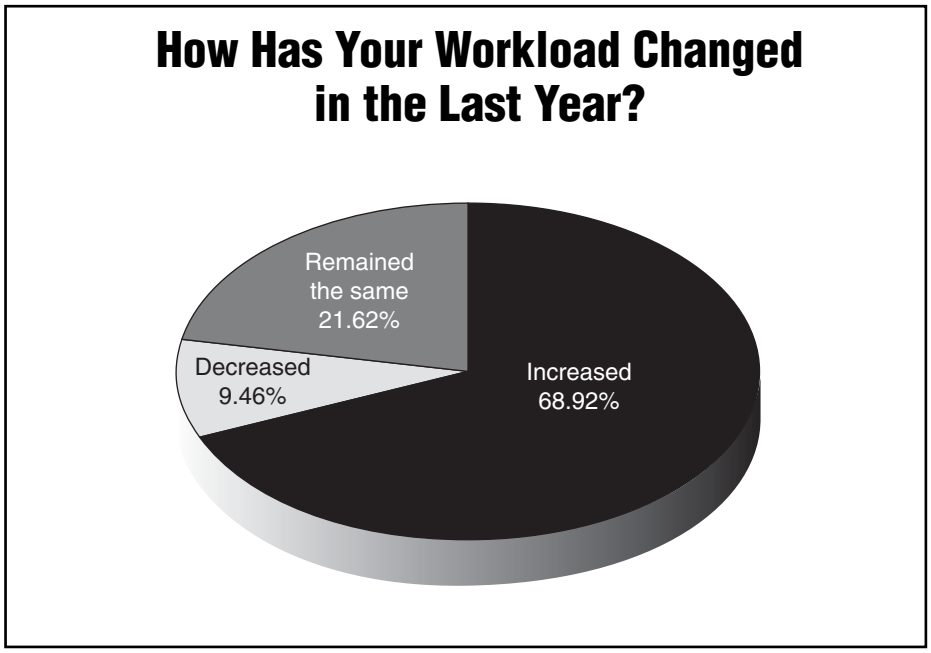
If Isidor did recruit college graduates, he says he'd be interested in English majors.

"I find that writing in our society is a dying art," Isidor says. "And I like people who can articulate well and listen, who can write and observe."

Also, the IRB has a number of employees with nursing backgrounds, Isidor says.

"But the truth is they don't teach anything about IRBs or human subjects research in colleges," he adds.





Advanced degrees

The 2007 salary survey shows that the IRB professionals who responded are well-educated. Only 13.51% have less than a bachelor's degree. And more than 60% of the respondents reported having completed at least some graduate work. More than 40% have earned a graduate degree.

IRB professionals are a well-educated group, despite the difficulty they face in advancing their education.

"Most of us have tried to go back and get advanced degrees," LoDico says. "But unless they have a very big staff, they have gone on, but never completed the degree."

LoDico says she personally is just two courses and a thesis away from receiving her master's degree.

Many institutions will provide tuition funding, but finding time to pursue an advanced degree is the problem, she notes.

Heavy workloads

"My average work week is 76 hours per week," LoDico says. "The range is rarely under 60 hours, and sometimes it's 80 and 90 hours—only surgeons work like this."

According to the 2007 salary survey, 56% of

respondents work more than 40 hours per week and 12% work more than 50 hours per week.

IRB administrators attend many meetings and are always multitasking, LoDico notes.

The salary survey respondents reported having seen increases in their workloads, with 68.92% showing an increase and only 9.46% showing a decrease.

The 2007 salary survey found that the IRB professionals who responded mostly are employed in hospitals (51.35%), with another 39.19% employed in an academic setting.

Also, survey respondents reported having less experience in working for an IRB than their ages might otherwise suggest.

For instance, more than two-thirds of respondents have worked for an IRB for six or less years. A little more than 17% have worked for an IRB between seven and 12 years, and about 14% have worked for an IRB for 13 or more years.

People who work for IRBs often find their jobs through serendipity, Isidor notes.

They start out in some other field, become interested in research and human subjects protection, and then end up working for an IRB.

"Most people started someplace else and ended up here at an IRB because there are no certifying degrees," LoDico says.

"I don't think people at age 11 or 12, when they're asked to describe a career path, will say they are going to work for an IRB," Isidor says. ■