Research tries to get a handle on IRB costs and variability

Smaller IRBs are less efficient, but connection of costs to quality of review still unclear

As IRBs seek to improve efficiency in their own operations, they often suffer from a lack of the most basic data about the costs of reviewing protocols.

The issues involved are not just financial — an IRB that doesn’t know what resources it’s using for which types of protocols can’t determine where to make changes to improve efficiency while retaining quality.

But in a useful development for human subjects protection, researchers are increasingly turning their attention to this issue, seeking out hard data about how much IRBs spend on all aspects of their work.

The studies already are uncovering interesting patterns and raising questions for institutions about how best to deploy their resources to protect research participants. But researchers are still trying to work out an important piece of the puzzle: How quality fits into the picture, and how best to measure that quality.

Economies of scale

Todd H. Wagner, PhD, a health economist with the Veterans Administration Palo Alto Health Care System in California, surveyed 81 IRBs at VA and VA-affiliated hospitals across the country and found strong economies of scale in IRB operations for a study published in August 2004 in the journal Medical Care.

Wagner’s group tallied the costs of operating an IRB, and the number of actions, or reviews of any kind, that the board conducted in a year.

It found that for small IRBs (those conducting up to 151 actions per year), the cost per action was significantly higher, at $2,781, than at a medium-sized IRB (up to 826 actions, at $416 per action) or a large IRB (larger than 1,637 actions, at $187 per action). Even within the group of 22 small IRBs, there was large variability of costs per action.

A more recent study found similar patterns, with lower-volume IRBs
spending, on average, more per protocol than mid- or high-volume IRBs.

That study, published in the August issue of Academic Medicine, drilled down into the data even further, examining the variability within each size of IRBs, and even within the various costs of IRB operations.

Author Margaret M. Byrne, PhD, a health economist and professor at the Miller School of Medicine, University of Miami, in Florida, says that deeper analysis of the numbers yielded some surprising results about what might be driving that persistent variability.

“What we found is there is a huge variability in the ratio of staff to board time,” Byrne says. She noted that at some IRBs, staff would report spending a third of the time that IRB members did reviewing protocols. At other institutions, staff reported spending 12 times as much time as IRB members performing that function.

“That tells you that IRBs across the country are doing things in very different ways,” she says. “We don’t know, of course, which ones are doing it correctly — most efficiently, to the highest quality. But it’s kind of unlikely that everyone is doing it well in such different ways.”

In addition, Byrne’s group found strong economies of scale for IRB costs where they wouldn’t necessarily be expected. The cost of IRB board member time spent on a protocol (based on the amount of time members spent on review, multiplied by a wage price) was substantially lower at higher-volume institutions.

“This indicates that board members at high-volume institutions are spending approximately one-third less time in reviewing each protocol than their counterparts at low-volume institutions,” Byrne wrote in the journal article.

What isn’t clear is the reason for these differences. Are the low-volume institutions simply less efficient? Are the high-volume IRBs too rushed in their reviews?

Byrne says that currently, we don’t have enough information to know what these numbers really mean as far as the quality of IRB review.

Getting at quality

“We could have one institution that is doing things very inefficiently, but also doing a very bad quality of reviews, and it could have the same costs as an institution that’s doing a very high quality of reviews but doing it very efficiently,” she says.

“So even if you found one institution that’s doing things great, and they had a certain cost, you couldn’t just look at the cost and say everyone who’s working at this cost is doing things right,” Byrne says. “You have to get down and measure the quality and the efficiency of the review process, and that is extremely difficult, of course.”
Byrne’s study was part of a larger project by the Consortium to Examine Clinical Research Ethics, a national group established at Duke University Medical Center to compile comprehensive data about oversight of clinical trials.

She says future consortium projects will try to get a better handle on the role of quality of IRB review, and its relationship to IRB costs.

“What we’re going to have to do is come up with some measures,” Byrne said. “What’s a measure of a good quality of review? Is it that you don’t have any adverse effects? That certainly is one measure, but you wouldn’t want it to be the only one.”

Wagner’s group tried to get at the thorny problem of determining the quality of an IRB, using three measures: whether the IRB’s administrator was certified by one of several nationally recognized certification groups; estimating the percentage of the IRB chairperson’s work that was compensated by the IRB; and the administrator’s response to a number of graded questions about the IRB’s efficiency and quality.

Wagner acknowledges that those methods have limitations, but says that other suggested measures, such as accreditation, have their own shortcomings.

“We really need IRBs to start to look inside their own systems and say, ‘What’s going on here?’ ‘How do we compare to other standards locally, nationally?’ They can look at their own system, but can they compare them to anything else to say whether it’s good?”

While there’s still much to know about IRB costs and their relationship to quality, Wagner says studies to date do give IRBs, particularly smaller ones, some questions to ponder about their own operations.

“For the very small IRBs in the world — those who do something less than 100 actions per year — the question is, would it be easier and better for your institution to affiliate with a larger one that’s a neighbor and do it all through them?” Wagner said.

“You give up some of the control, but maybe you get a faster, better product. This really is for those (smaller IRBs), because we know that the economies of scale curve is so steep on the small side.”

Wagner says medium and large operations should consider a different issue — possibly contracting out particular types of protocols that require large expenditures of resources or that are in areas that require special expertise.

He notes that many boards are beginning to contract out industry-sponsored protocols to commercial IRBs to better manage their workloads.

“If an IRB is an expert in clinical trials, then maybe they should send out health services or qualitative work because maybe the IRB members just don’t know it as well,” Wagner says.

Currently, though, Wagner says IRBs seeking to make these decisions are hampered by the lack of data.

“We’re beginning to see protocol tracking systems that can tell you what protocol is at what stage and which ones are coming up for renewal. But none of them track it to the level of how much effort you put into a particular protocol.”

He predicts that the next decade will be one of rapid change in IRB management, as institutions try to get a handle on these issues.

“I think we’re going to see a sort of hold-on-to-your-seats type change, and I really hope that people keep their eye on the data — that it be evidence-based, not I-heard-it-through-the-grapevine change, but evidence-based change.”

Sources


---

Do research subjects retain informed consent details?

Small subset has trouble remembering information

A small but notable percentage of veterans in a long-term drug study were unable to retain some of the simplest information about it — including the purpose of the study, the name of the drug and its main side effect — for the entire course of the trial.

The retention study’s author notes that while most of the participants were able to remember this information, the group that didn’t was disproportionately older, less educated and non-white.

Joan M. Griffin, PhD, a researcher at the Minneapolis VA Medical Center, in Minnesota, says she was surprised by the variation in retention based on age, race and education.

“It’s really unclear what’s going on in this small minority that doesn’t understand these
things,” she says. “But if it is the case that these
groups don’t understand the language of clinical
trials and are just in [the trial] and aren’t
informed, there are obviously gaps that we need
to address from the get-go.”

She says the findings suggest that researchers
must work harder to simplify informed consent
for all participants, and should reiterate key
information as needed in long-term clinical trials.

“With these basic things, if you can really
inform the patient over and over again, I think it
would be helpful,” Griffin says.

Survey part of cholesterol study

The retention study was published in the
October 2006 issue of Contemporary Clinical Trials.
The survey was added to the end of a clinical
trial conducted at VA hospitals during the 1990s
among male veterans with heart disease and low
levels of high density lipoprotein (HDL) choles-
terol. The VA HDL Intervention Trial, a double-
blinded, randomized, placebo-controlled study,
looked at whether raising HDL cholesterol using
medication prevented heart attacks and death from
heart disease.

Informed consent for the trial included expla-
nation by a study coordinator about several key
points: the purpose of the trial, randomization,
the name of the medication (gemfibrozil), possible
risks and benefits, a patient’s right to withdraw
from the study and the drug’s potential side
effects, including the main side effect, gallstones.

Copies of the informed consent form also were
provided to patients. If the coordinator deter-
mined that the patient couldn’t understand the
consent procedure, he was considered ineligible.

At the end of the five-year trial, during the
patient’s final follow-up visit, he was asked three
questions about the study: The purpose, the
name of the drug and its main side effect.

Out of 1,789 participants who answered at
least one of the questions (missing answers were
counted as incorrect):

• 35.3 percent could not identify the purpose
  of the study;

• 20.4 percent did not know the name of the
  medication;

• 68.9 percent couldn’t state the main side
  effect of the medication.

Of the total group, non-white participants were
more likely to get two of the three questions
wrong. More than half (54.3 percent) of non-white
participants could not identify the purpose of the
study, while 27.2 percent couldn’t name the med-
ication. But more non-white participants were
able to identify the main side effect (64.2 percent
incorrect, compared to 69.3 percent of whites).

For each question, participants who were older
than 70 were more likely than the group as a
whole to answer incorrectly, as were those with
less than a high school education.

It’s possible, Griffin says, because of the age of
the subjects, that cognitive decline may have led
to their forgetting the facts of the trial.

“This brings a note of caution to people who
are conducting studies,” she says. “If they are
working with populations of older adults, they
really do need to take additional time in the con-
senting process, and then probably reiterate that
information over the course of the study.”

Griffin emphasizes that the majority of the par-
ticipants surveyed knew the most basic details -
the study’s purpose and the name of the drug.

“The point we’re trying to make in the paper is
that even though the majority of people did know
that basic rudimentary information, the propor-
tion that didn’t are those that are underrepre-
sent ed in clinical trials,” she says. “That’s where we
really need to work because those may also be the
people who are most likely to quit a clinical trial.”

And she points out that the details asked for in
the study were the most fundamental facts about
the clinical trial, leading to concerns that more
complicated issues have even lower retention.

“We haven’t even tackled some of the things like
issues around randomization, which I think are
very difficult for people to understand,” Griffin
says. “There’s risk assessment — it’s been shown in
the literature that very few people understand risk.”

One limitation of Griffin’s study is that veterans
were only asked the study questions at the end of
the clinical trial. There was no data to show how
many knew the information at the outset of the
trial. But because the information asked of the
participants was so basic, Griffin says she finds it
hard to imagine how they could have been signed
up for the study without knowing it.

Simplify and repeat details

Of the three questions asked, the question
about side effects drew the largest number of
incorrect responses. Griffin says the group that
answered it correctly simply may have been
more interested in that information or may have
suffered the side effect themselves, so they
remembered it better.
By far, the best remembered fact about the study was the name of the drug, and Griffin says that may point to repetition as a potent tool for helping patients remember details of a clinical trial.

“Perhaps one of the reasons that people knew the name of the study medication was that it was reiterated so frequently when they came in for their medication,” she says. “We can learn a lot by repeating that information.”

But Griffin says she hopes the results of this study don’t cause IRBs to simply demand that researchers repeat information to subjects over and over, or to target groups such as minorities for special treatment.

“I worry about bias, the kind of stereotyping that can go on,” she says. “You end up having a study and you assume that this population is not going to understand it more because of their age or the color of their skin.”

She says a better response to these concerns would be to simplify the process of informed consent for everyone, with extra repetition of information in more complex studies. Co-ordinators should allow participants to take the time they need to truly understand the information, rather than rushing through a rote explanation.

“Target the information to the lowest reading level possible, because everybody can benefit that way,” she says. “If it’s a more complex trial, you could have more reminders throughout the trial.”

Griffin noted another common teaching tool for health literacy, the “teach back” method, in which the coordinator goes over the material, then asks the participant to repeat the information back in his own words.

In addition to improving understanding of informed consent and retention of study details, these strategies also could help fight attrition rates, which could include groups of people who really didn’t understand the study.

“It may be that those people are that same population that may be most likely to quit, and there may be another part of that population that didn’t even participate in the study, because consent forms can be scary,” Griffin says. “And if one of the things that we’re trying to do is represent the underrepresented, then we need to make consent forms simpler from the very beginning.”

Source

IRBs sometimes reject an investigator’s request to use the short informed consent form, even when it would meet regulatory and ethical standards.

The short form is a generic informed consent form that can be translated into different languages and used in lieu of a detailed informed consent document when a participant does not speak or read the dominant languages of a particular study’s subject population, says David Borasky, CIP, director of the Office of International Research Ethics for Family Health International of Research Triangle park, NC. Borasky spoke about the short consent form at the National Human Subjects Protections Conference called, “Crossing the Line: What is Acceptable Risk?” held Sept. 25-26, 2006, in Durham, NC.

The regulations [45cfr46.117(b)(2) and 21cfr50.27(b)(2)] permit the short form that is translated in that language to be used to document informed consent. When using the short form, the consent process must be witnessed, and there has to be a summary script approved by the IRB that a translator will use to informed potential participants, Borasky explains.

The script summarizes what is in the regular consent form, covering all of the main elements, and then the subject is asked to sign the short form in their own language and is also given copies of the English-version consent form that is signed by the study staff, Borasky adds.

Specifically, the regulations say that only the short form is to be signed by the subject or the representative, but the witness must sign both the short form and a copy of the summary. And the people obtaining consent must sign a copy of the summary.

Federal regulations permit that process, but sometimes IRBs are uninformd about how and why the short form is used.

When Denver, CO, investigators first approached IRBs about a tuberculosis study and requested to use the short informed consent form for the handful of participants who speak a minority language, the IRBs flatly refused, recalls William Burman, MD, medical director of the infectious diseases clinic at the Denver Public Health Department in Colorado. Burman also spoke about the short form at the National Human Subjects Protections Conference.
The answer we got back was ‘You can’t do it,’ because the IRBs weren’t aware of this aspect of the regulations,” Burman says. “We told them, ‘We’re not making up anything new — this has always been in the regulations.’”

Once investigators communicated in greater detail the existence of the short form procedure in the regulations and how they intended to use it, the IRB endorsed the short form and even had it published in 20 different languages on the Web site for affiliated investigators to see and download, Burman says.

“In general, at our site, we’ve had increasing use of the short form, but it’s still not accepted at every site,” Burman notes.

The consent form makes perfect sense for the Denver TB research, he says.

“We deal with patients who come through from all over the world, so we can predict some languages that will be very common, and one of those for us is Spanish,” Burman says. “Fifty to 60 percent of our patients speak Spanish, so in that case the appropriate thing to do is have the full consent form translated.”

But there also are patients from remote areas of the world who are eligible and ideal candidates for a clinical trial involving TB, but if there is no mechanism allowing the use of a short form, the site can’t enroll them, he explains.

To have the lengthy informed consent document translated into an Ethiopian patient’s language, for instance, would be tremendously expensive, Burman adds.

“So the short form enables us to offer enrollment to patients who come from areas of the world where we can’t predict there will be a significant number of patients from that area,” he says.

Patients who are eligible for a study and the short form are provided a translator by telephone, Burman says.

“These are the same translators we use for clinical care,” he says. “We don’t have translators for all languages, so we use a commercial translation service that is expensive.”

Regulations require that the translator use an approved summary of the study, and the translator is expected to go over the short form word-by-word, because not all patients are literate, Burman adds.

“Rather than create an independent document that is IRB approved for a study, we use the study’s original consent form,” Burman says.

The translator discusses the entire consent form with the subject in a conversation that could take more than an hour, he adds.

This way the clinical trial site can be certain the subject knows what is in the long consent form without having to spend the thousands necessary to have it translated into another written document.

And this method ensures a strong informed consent process, Burman notes.

“Ideally, the use of the short form could refocus the consent process back to where it belongs: to oral communication,” Burman explains. “Study after study says that what is remembered by research subjects is not what’s in the informed consent form, but what is said.”

While the short form can be a useful tool for some sites, it should only be used with proper preparation and without compromising the rights of potential participants, Borasky says.

One of the dangers of using a short form and oral translator is that the quality of the translation will not be ideal, he says.

“Anytime you use translators, you need to chose them carefully because an inexperienced translator who is not familiar with the [research] language used in the consent form could have some variability in the quality of information given to subjects,” Borasky says.

“Another concern is if you did enroll someone successfully with the short form, what would happen if the person had questions later on and nobody on the study team could speak the person’s language and answer those questions,” Borasky adds.

Even finding a witness to watch the subject sign the short consent form poses potential problems because the regulations don’t define what a witness is, and if a family member is used, this would be less than ideal, he says.

“I think the short form should be considered in situations where enrollment of people qualified for the short form is compelled for reasons of justice,” Borasky says. “I think when investigators are looking to use the short form, it’s not merely a matter of convenience — they have to have a compelling reason why.”

PRIM&R takes IRB training to international sites

Workshops held in Africa, Mexico

The rapid growth in international research is providing challenges for human subjects protection in other countries, many of which lack the resources that American IRBs have.
The Public Responsibility In Medicine and Research (PRIM&R) program is gearing up to help these countries improve their means of reviewing research and collaborating with U.S. institutions.

PRIM&R already has participated in two conferences in Africa on human subjects protection practices, says PRIM&R Executive Director Joan Rachlin, JD, MPH, in Boston, MA.

She says that at the most recent conference, held last year in Durban, South Africa, PRIM&R introduced an REC Administration 101 program, adapted from PRIM&R’s existing “IRB Administration 101” program offered in the United States (Many countries outside the U.S. refer to their IRBs as research ethics committees, or RECs).

PRIM&R and its REC Administration 101 workshop in Durban were selected recently for an honorable mention in the 2006 Associations Make A Better World Awards.

Rachlin and others involved in the program say the goal of their continuing efforts to provide IRB training in other countries is to provide the U.S. perspective on human subjects protection — not to impose a set of U.S. practices on the rest of the world.

“The main thing we made clear was we weren't there to tell them what to do, we were there to tell them how we do it — they have to figure out how they want to do it,” says Elizabeth Bankert, MA, IRB administrator at Dartmouth College, Hanover, NH. Bankert was one of two people who presented the REC Administration 101 program at the Durban conference, and presented a similar program in Mexico City this past summer.

“I go overboard to make sure I come in with that attitude that we’re here to work with you — that it’s your perspective that’s the most important. These are your people and your country, you need to teach us,” Bankert says.

**Building capacity**

Rachlin says PRIM&R’s goal is human subjects protection capacity building in parts of the world such as Africa, which has seen a tremendous increase in clinical research.

“PRIM&R has been very committed to trying to help those who are doing research internationally, particularly in under-resourced or resource-scarce countries,” she says. “We want to ensure that they have access to both the materials and the information necessary to develop strong human protection programs.

“It’s a very significant challenge because of the technological limitations. Quite often people in resource-scarce countries don’t have the access to technology, or it’s insufficient for the kinds of electronic training that we take for granted here.”

Rachlin says PRIM&R had participated two years ago in a conference in Malawi, in southern Africa. Last year, the organization was invited to a second conference in Durban, at which research professionals from 14 African nations were represented.

“We decided that since we were going to be part of the conference, perhaps it would be helpful to bring one of our short courses over, and give it free of charge to those who were coming for this broader ethics consortium,” Rachlin says.

For content, Rachlin turned to the IRB Administration course developed by Ada Sue Selwitz, MA, director of the Office of Research Integrity at the University of Kentucky, and Susan Kornetsky, MPH, CIP, director of clinical research compliance at Children’s Hospital in Boston. Selwitz and Kornetsky worked with the two women who would be presenting the program in Durban — Bankert and Karen Hansen, director of the Institutional Review Office of the Fred Hutchinson Cancer Research Center in Seattle, WA — to adapt the program for use at the African conference.

IRBs or RECs in other countries still are bound by U.S. regulations if federal funding is used for a clinical trial, so much of that content was kept for the African version.

Bankert says the chief issue in adapting the program was recognizing the different level of resources available to the African RECs.

“They’re still looking at the one-person or no-person IRB office, they’re not yet looking at it at an institutional level,” she says. “We try to work with them at the point where they are, starting with getting policies and procedures written down. We could have stayed with them another day and just sat with them and written policies and procedures, because many of them didn’t have those.”

Bankert says she also believes that African RECs work under different pressures from those experienced by IRBs in the U.S.

“The Ministry of Health and the institutions really need money so badly,” she says.

She noted that some RECs were struggling with decisions over whether to allow Phase IV “post-marketing surveillance” studies, which some U.S. institutions won’t do.
“Some people really consider it a marketing study,” Bankert says. “It can bring in some money to an institution, but is that really the mission of a research academic medical institution?”

“There was one institution in Johannesburg that had been asked to do Phase IV studies and it bothered them, because they’re not even sure that their population would ever actually use the drug. So they knew they were doing it for the funding, not necessarily for the long-term population. That was troubling to them.”

Rachlin enthused about the work the four women did to create a curriculum that served its international audience.

“It was adapted to be as responsive as it could be to the needs of those on the continent of Africa,” she says. “It was not just taking a canned curriculum, exporting it to Durban and saying, ‘Well, here you are, hope you like it, hope most of it helps.’ It was a very different process and one we’re very proud of.”

Bankert and Rachlin say they were impressed by the enthusiasm of the REC professionals, as well as their understanding of the international regulations that apply to human research.

The Durban conference has led to the creation of an African professional society, the Partnership for Enhancing Human Research Protections — Africa (PEHRP-A). That organization has its own newsletter, and hopes to hold another conference next year, Rachlin says. She plans for PRIM&R to participate in that one, as well.

In the meantime, Bankert gave a similar presentation in Mexico City this past summer. She says the experience was different from the one in Africa, most notably because the African participants were more conversant in English, whereas she required a translator in Mexico.

Bankert says her international experiences have changed her own understanding of international research, and she’d like to see more collaboration between U.S. IRBs and the RECs in countries where research is conducted. Currently, she says, she’s found that these boards rarely are in contact.

Rachlin says PRIM&R will work to set up more workshops in various parts of the world, and continue its program of bringing human subjects protection professionals from other countries to attend conferences in the United States.

Currently, PRIM&R has been funding these efforts from its own reserves, but hopes to apply for grant money to expand the program.

“We do expect that within the next year, we’re going to start advertising our willingness and ability to teach this in other international countries and we’re very excited about that,” Rachlin says.

In each case, though, she says the organization wants to proceed carefully, to provide the most useful program for the international audience.

“We want to make sure we have the right partners, the right stakeholders, the right curriculum, the right teachers,” Rachlin says. “We want to make sure that the case studies we use aren’t Western-centric. So it’s a fairly long preparatory process. But the Durban session was such an exciting, well-received, toe-in-the-water effort, we’re truly excited about next steps and we’ll hopefully engage in this work for a long time to come.” ■

---

**IRB Insider**

[Editor's note: This occasional series, beginning with this issue of IRB Advisor, features an IRB that has evolved and improved through the IRB director’s creativity and development of best practices. If you and your IRB office have solved an interesting challenge or developed a new twist to an old practice and would like to share your story with us, please contact Managing Editor Leslie Hamlin at leslie.hamlin@AHCMedia.com.]

---

**Small IRB develops, finds ideal solutions to problems**

*Achieving IRB quorum, measuring quality, etc.*

The IRB office at Memorial Medical Center in Johnstown, PA, began as many small IRBs do, with one part-time employee. As the workload increased to about 80 protocols per year, the office turned the part-time position into a full-time administrator position, and organizational procedures were put in place.

But despite a structured daily routine and office support, the IRB has experienced some growing pains, which have resulted in the IRB office developing its own best practices to meet these challenges.

“I came into the IRB office with a background in medical records, but no previous IRB and research experience,” says Paulette M. Vandzura, MA, CIP, the IRB administrator for Memorial Medical Center.

“One of my strongest personality characteristics is that I structure day-to-day processes, streamline them, and live by the rule of ‘Do it once,’” she says.

The IRB’s chairman served as Vandzura’s mentor and helped her meld her skills with the needs of a fulltime IRB office, including paying
attention to the details that would enable her to streamline processes and improve quality.

Here are some of the IRB challenges and Vandzura’s best practice answers:

- **Problems achieving IRB quorum:** One of the recent challenges the IRB faced was a repeated loss of quorum, which was a dramatic problem to investigators who would then have to wait another month to have their protocols reviewed, Vandzura says.

  “Sometimes when the timing was critical, we’d set up a teleconference call,” Vandzura says. “But those are difficult for members to attend.”

  In one 12-month period, the 11-member IRB lost quorum three or four times, which is a significant problem for a small organization, Vandzura says.

  The reasons why some of the IRB members were unable to attend certain meetings were understandable because they had clinical responsibilities that took priority over the IRB role, she says.

  “For example, we have on the board a chairman of the department of emergency medicine,” Vandzura explains. “And we have a busy ER, so when the ER is busy, he needs to be there.”

  So the solution was to recruit volunteers to be alternate members of the IRB, Vandzura says.

  The IRB recruited four alternate members, including one additional community member, she says.

  “The first time we picked a community member alternate, the person was an educator,” Vandzura notes. “We invited him because at some point he had had a conversation with our chair and had expressed an interest in the IRB.”

  This member served for some months, but had to resign when promoted to state board of education job.

  “His replacement was a woman from a higher education background whom I knew personally,” Vandzura says. “I knew her work traits and attitude and I thought she would be interested when approached.”

  The three alternates who have scientific and medical backgrounds were all people who had contacted the IRB as interested parties, Vandzura says.

  “We have two physicians who spoke up one day and said they were interested in the IRB and research and would like to serve if we ever had an opening,” she recalls. “So we talked it over and decided to ask them to join us as alternate members.”

  The IRB alternates receive the same training and have the same requirements as full voting members. They are asked to view a video on protecting human subjects, and they are given an IRB handbook and HIPAA handbook, Vandzura says.

  “We ask them to read the Belmont Report and Nuremberg Code, and we ask them to sign a document saying they have read those items,” she says. “We also provide one in-house seminar every year for IRB members, and it’s focused around an issue involving IRB work.”

  Each month, the alternates are sent the full IRB protocol packet, and they are expected to show up prepared, as though they will have a vote that month, Vandzura notes.

  Alternate members also are included in the annual recognition dinner and in the awards program when they have achieved five and 10 years of service.

  “I’m the only one at the meeting who is sure who is voting, and everyone participates in the discussion,” she says. “Even if alternates raise their hands to vote when their vote isn’t necessary, it doesn’t matter because I know who is there and who can vote and which votes count.”

  So far there have not been any highly contentious issues in which the vote was very close, Vandzura adds.

  Since adding the four alternates, the IRB hasn’t lost a quorum, although it would have lost quorum several times without their presence, she says.

- **Measure IRB quality:** The IRB uses a customized questionnaire to gather the opinions of research investigators, nurse study coordinators, and others in research about the IRB.

  The IRB used as a guide the IRB Researcher Assessment Tool (IRB-RAT), developed by Patricia Keith-Spiegel and Gerald P. Koocher of the Children’s Hospital and Harvard Medical School in Boston, Vandzura says.

  But the adapted questionnaire has only 13 questions.

  “We felt we wouldn’t get as good a response if we sent out a questionnaire as detailed and with as many responses as the IRB-RAT requires,” Vandzura says.

  The questionnaire was sent to 49 people who were asked to make an anonymous response by Oct. 20, 2006. Within a couple of weeks, responses came from about one-third of those queried, she says.

  “We just said their feedback would allow us to look at our performance and give us a sense of perceived strengths and weaknesses and areas where we might improve our service,” Vandzura says.

  The questionnaire features questions, such as these:

  - Does the IRB demonstrate respect toward investigators?
  - Is our Web site organized and easily navigated,
and does it provide the documents you feel you need?
- Does the IRB offer helpful suggestions for how to improve your protocol?
- If the IRB requires revisions, do you receive a detailed summary that’s easy to understand in terms of what’s required?

With the results, Vandzura will create a spreadsheet and statistical analysis of the responses and then publish these on the Web site.

“I’ll probably send the investigators queried a report and mention what the IRB has decided to do with the information,” she adds. “Then I’ll open the dialogue and ask for additional help in improving the IRB Web site.”

In the responses thus far, there appears to be a trend regarding lukewarm reviews of the IRB’s Web site, Vandzura notes.

“It’s not getting rave reviews,” she explains. “It’s pretty much getting ho-hum reviews on whether it’s easy to navigate and whether materials provide good guidance.”

So Vandzura plans to discuss possible improvements with investigators or to send out another questionnaire to find out what they think is lacking and where improvements are needed.

- **Use Microsoft Word’s auto-text:** “It’s wonderful for saving yourself carpal tunnel syndrome,” Vandzura notes.

“When you’re in a Word document, and there’s something you want to put in auto-text, you highlight and open auto-text,” she explains. “I use the number of the research study.”

Anytime Vandzura needs to put the study’s number into a report or letter, all she has to do is type the IRB’s four-digit tracking number, and the research study title pops up.

---

**2006 Salary Survey Results**

**What is Your Annual Gross Income?**

<table>
<thead>
<tr>
<th>Income Range</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than $30,000</td>
<td>4.11%</td>
</tr>
<tr>
<td>$30,000-$39,999</td>
<td>10.96%</td>
</tr>
<tr>
<td>$40,000-$49,999</td>
<td>17.81%</td>
</tr>
<tr>
<td>$50,000-$59,999</td>
<td>15.07%</td>
</tr>
<tr>
<td>$60,000-$69,999</td>
<td>16.44%</td>
</tr>
<tr>
<td>$70,000-$79,999</td>
<td>9.59%</td>
</tr>
<tr>
<td>$80,000-$89,999</td>
<td>8.22%</td>
</tr>
<tr>
<td>$90,000-$99,999</td>
<td>2.74%</td>
</tr>
<tr>
<td>$100,000-$129,999</td>
<td>6.85%</td>
</tr>
<tr>
<td>$130,000 or more</td>
<td>8.22%</td>
</tr>
</tbody>
</table>

The average income of an IRB professional is $40,000-$49,999, the average facility location is in an urban area, the average time worked in the IRB field is 4-6 years, the average amount of hours worked per week is 41-45, and the average age is 51-55.
How Long Have You Worked in Your Present Field?

How Many Hours a Week Do You Work?

What is Your Age?

COMING IN FUTURE MONTHS

- Waivers of consent for emergency research
- Mandatory clinical trials registry: Are we any closer?
- Create a great 'how to' procedure book
- Here are some ideas in solving substance abuse research problems
CE/CME Objectives

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

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

Physicians and nurses participate in this medical education program by reading the issue, using the provided references for further research, and studying the questions at the end of the issue. Participants should select what they believe to be the correct answers, then refer to the list of correct answers to test their knowledge. To clarify confusion surrounding any questions answered incorrectly, please consult the source material.

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

18. True or False: A survey of IRBs showed a large variability in the ratio between the amount of time IRB staff members and their board members spent on protocols.
A. True
B. False

19. What three factors were found to affect the ability of veterans to remember details about a five-year clinical trial in which they were enrolled?
A. Age, gender and military rank
B. Age, cognitive function and level of education
C. Age, race and level of education
D. Years of service, military rank and level of education

20. Which defines the informed consent short form?
A. The short form is a version of the informed consent document that includes more accessible language, greater use of white space, bullets, and bold-faced headings, and which does not include unnecessary disclaimers and language.
B. The short form is a Braille version of the informed consent document.
C. The short form is a generic informed consent form that can be translated into different languages and used in lieu of a detailed informed consent document when a participant does not speak or read the dominant languages of a particular study’s subject population.
D. None of the above.

21. A small IRB recently came up with a strategy for ensuring quorum at IRB meetings. What change did it make?
A. The IRB required members to pay a fine if they had an unexcused absence from voting.
B. The IRB recruited four alternate members who are trained and treated the same as regular IRB members, but whose vote counts when quorum is needed.
C. The IRB hired three additional community members, who fill in when quorum is needed.
D. All of the above.

Answers: 18. (a); 19. (c); 20. (c); 21. (b)