IRB ADVISOR

YOUR PRACTICAL GUIDE TO INSTITUTIONAL REVIEW BOARD MANAGEMENT

DECEMBER 2014 Vol. 14, No. 12; p. 133-144

INSIDE

Follow us on Twitter @IRBAdvisor

AHC Media

OHRP issues draft guidance on standard of care research

Guidance issued in response to Support study controversy

A year after its public meeting on the Support study, the Office of Human Research Protections (OHRP) issued a draft guidance to clarify its thinking on the disclosure of reasonably foreseeable risks in standard of care research.

The guidance, titled "Draft Guidance on Disclosing Reasonably Foreseeable Risks in Research Evaluating Standards of Care," was released by the organization in late October. OHRP developed the draft guidance following a public comment and meeting in August 2013 after the fallout from the 2010 Surfactant, Positive Pressure, and Oxygenation Randomized Trial (Support).

The National Institutes of Health (NIH)-funded study included 23 research institutions under the coordination of the University of Alabama Birmingham and tested oxygen levels for nearly 1,300 premature infants. The study intended to find the optimal oxygen concentration for the premature infants. The infants receiving higher levels of oxygen developed retinopathy and other eye disease twice as much as the infants in lower oxygen levels. Those receiving lower oxygen levels had higher rates of brain damage and mortality.

> OHRP REQUIRED CORRECTIVE ACTION, WHICH TOUCHED OFF A DEBATE IN THE RESEARCH ETHICS WORLD.

Standard of care debate

In March of 2013, OHRP sent UAB a determination letter stating that the oxygen saturation levels portion of the study was in violation of informed consent requirements

Financial Disclosure: Financial Disclosure: Editor **Melinda Young**, Executive Editor **Russ Underwood**, Associate Managing Editor **Jill Drachenberg**, and Physician Reviewer **Mark Schreiner**, MD, report no consultant, stockholder, speaker's bureau, research, or other financial relationships with companies having ties to this field of study.

IRB ADVISOR

IRB Advisor,
ISSN 1535-2064, is published monthly by
AHC Media, LLC
One Atlanta Plaza
950 East Paces Ferry Road NE, Suite 2850
Atlanta, GA 30326.

Periodicals Postage Paid at Atlanta, GA 30304 and at additional mailing offices.
GST Registration Number: R128870672.

POSTMASTER: Send address changes to:
IRB Advisor
P.O. Box 550669
Atlanta, GA 30355.

SUBSCRIBER INFORMATION:
Customer Service: (800) 688-2421.
customerservice@ahcmedia.com.
www.ahcmedia.com
Hours of operation: 8:30 a.m.- 6 p.m. Monday-Thursday; 8:30 a.m.-4:30 p.m. Friday, EST.

SUBSCRIPTION PRICES:
Subscription rates: U.S.A., Print: 1 year (12 issues) with free AMA Category 1 Credits™ or Nursing Contact Hours, $419. Add $19.99 for shipping & handling. Online only, single user: 1 year with free AMA Category 1 Credits™ or Nursing Contact Hours, $369. Outside U.S., add $30 per year, total prepaid in U.S. funds.

MULTIPLE COPIES: Discounts are available for group subscriptions, multiple copies, site-licenses or electronic distribution. For pricing information, call Tria Kreutzer at 404-262-5482. Back issues, when available, are $75 each. (GST registration number R128870672.)
Missing issues will be fulfilled by customer service free of charge when contacted within one month of the missing issue's date.

ACCREDITATION: AHC Media, LLC is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

AHC Media, LLC designates this enduring material for a maximum of 18 AMA PRA Category 1 Credits™. Physicians should claim only credit commensurate with the extent of their participation in the activity.

AHC Media is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation. This activity has been approved for 15 nursing contact hours using a 60-minute contact hour. Provider approved by the California Board of Registered Nursing, Provider #14749, for 15 Contact Hours.

This activity is intended for clinical trial research physicians and nurses. It is in effect for 36 months from the date of publication.

Opinions expressed are not necessarily those of this publication. Mention of products or services does not constitute endorsement. Clinical, legal, tax, and other comments are offered for general guidance only; professional counsel should be sought for specific situations.

EDITOR: Melinda Young.
ASSOCIATE MANAGING EDITOR: Jill Drachenberg, (404) 262-5508
(jill.drachenberg@ahcmedia.com).
DIRECTOR OF CONTINUING EDUCATION AND EDITORIAL: Lee Landenberger.

EDITORIAL QUESTIONS
Questions or comments?
Call **Jill Drachenberg**,
(404) 262-5508.

and that researchers did not fully explain the risks involved in the study. OHRP required corrective action, which touched off a debate in the research ethics world. The August 2013 public meeting brought comments on both sides of the issue, with researchers and bioethics leaders speaking in support of UAB and others who supported OHRP's determination. *(For more information on the Support study and the public debate, see "Informed consent, standard of care debated at OHRP meeting" in the October 2013 issue of* IRB Advisor*, page 109.)*

According to the draft guidance, the public debate "raised a number of questions, including: (1) what risks to subjects are presented by clinical trials studying interventions that are standard of care in the clinical treatment context, such that an IRB must evaluate those risks in relation to the anticipated benefits of the research; and (2) how an IRB should assess whether those risks are reasonably foreseeable such that the risks must be described to subjects in the informed consent process."

The draft guidance gives clarity to IRBs and researchers on how to apply regulations 45 CFR Part 46 when evaluating studies with multiple standards of care. "It explains OHRP's position that in general the reasonably foreseeable risks of research in a study include the already identified risks of the standards of care being evaluated as a purpose of the research when the risks being evaluated are different from the risks some of the subjects would be exposed to outside of the study," the document states. "Reasonably foreseeable risks must be described to prospective subjects when seeking their informed consent in accordance with 45 CFR 46.116(a)(2)."

Defining standards, risks

The guidance addresses the following questions.

• What are "standards of care"?

OHRP uses "standard of care" to refer to medically recognized standards of care: treatments and procedures accepted and typically used by healthcare professionals to treat certain conditions or diseases.

• What are "risks of research" in studies evaluating risks associated with standards of care?

The risks of a standard of care are considered risks of research if, "(1) a standard of care that at least some of the individual subjects will be assigned to receive will be different from the standard of care that they would have received if they were not participating in the study, and (2) there might be different risks associated with those standards of care," according to the guidance.

It is often the case that the risks associated with one standard of care are different from the risks of another standard, the guidance states, and do not include the risks associated with the subject's condition or other standard of care treatments he or she may be receiving.

• When is evaluating a risk in a research study considered to be a "purpose" of the research study?

According to OHRP, "research should be limited to evaluating those risks that are sufficiently important to justify the conduct

of the study," the guidance reads. "The purposes of such studies should not be construed as necessarily including each and every one of the outcomes that may be measured as part of the study, but that are not part of the fundamental reasons for conducting the study." The evaluation of a risk is considered a purpose of research only if the study is designed to investigate a particular risk, it states.

• Are the risks of research associated with the purposes of studies of standards of care "reasonably foreseeable risks" that must be disclosed to prospective subjects in the informed consent process?

Reasonably foreseeable risks must be disclosed to subjects in order for them to make an informed decision as to whether to participate in research, regulations state. As far as standard of care studies, "if the rationale for evaluating a risk associated with a standard of care is sufficient to warrant conducting the research, then OHRP's view is that, in general, the research risk being evaluated has been recognized as a sufficiently possible outcome so as to make it a 'reasonably foreseeable' risk, and the regulatory provision applies.

If researchers design and conduct a study for the purpose of evaluating a particular risk, then that risk is significant enough that it should be disclosed to the prospective subjects who are actually exposed to it," the guidance reads.

Public comment

OHRP is currently receiving public comment on the draft guidance. The comment period for the guidance ends on December 23, 2014. The full document can be found at http://www.hhs.gov/ohrp/newsroom/rfc/comstdofcare.html. ■

Ethics in age of 'big data' go beyond privacy issue

Facebook was just beginning

Human research protection program directors and IRB members witnessed a very public ethical dilemma this past summer when debates raged over Facebook's social media study. Public rebukes of studies involving big data and social media are fairly rare, but these studies can raise all kinds of ethical challenges.

"It goes beyond privacy," says **Ryan Spellecy**, PhD, an associate professor of bioethics and medical humanities at the Medical College of Wisconsin in Milwaukee.

"This is challenging our usual ways of protecting human subjects, and it moves beyond privacy in the sense that it's an opportunity for us to engage our communities in conversations that try to adhere to respect of persons," Spellecy says.

Think beyond HIPAA authorizations and consider how IRBs can engage research participants to find out their preferences when studies involve large data warehouses, he says.

One hurdle to having this type of ethical debate is that IRBs often think of the respecting persons rule as synonymous with the informed consent process, says **Emily E. Anderson**, PhD, MPH, assistant professor of bioethics at Loyola University Chicago in Maywood, IL.

"We're interested in responding beyond that process," she says. "Engaging participants in the discussion is one way of figuring out what respect means, and anything beyond the individual consent form is where we're at — redefining respecting persons."

Here are some of the main issues that need to be discussed in the era of big data, experts say:

• What do you do when informed consent (IC) doesn't fit a study?

"In these large data warehouses, the IRB can simply waive consent, and they've met regulatory obligations," Spellecy says.

But if consent is waived, how else can an IRB make certain the study shows respect for persons? he asks.

"If we can't get informed consent when the study is running, then maybe we can be foresighted and get community input about the design itself and the way data is handled to show respect for persons," he adds.

One reason why informed consent is a challenge in many of today's studies is because

regulations were written for past problems, developed in response to previous abuses, Anderson says.

"They're not forward-looking, and they're focused on the clinical research environment where there is a one-to-one patient/researcher relationship," she says.

"I think the issues we're struggling with around big data are not unique to big data," Anderson adds. "They're struggling with the same thing in oral history, where research doesn't look the way informed consent looks."

• Was data collected in an ethical manner?

When a researcher submits a study involving big data, one of the first questions an IRB might consider involves whether the data's collection was done ethically, Anderson says.

If the answer isn't "yes," then maybe the study should not be done, she says.

Often, there isn't a clear answer. Data could have come from a different academic institution or source, and researchers might not have any control over how it was collected, she notes.

An institution could develop standards for data collection and use. If these standards are agreed upon by multiple institutions, then IRBs and researchers might have access to information that they know has been collected ethically.

Still, even if an academic research organization requires only the use of data collected in an agreed-upon ethical manner, someone likely will use the collected data.

"When I speak with health services researchers, they see data that other nonacademic entities have, and they'd love to get their hands on it because they could do amazing things with it," Spellecy says. "The amount of data out there is unprecedented, and it doesn't just pose new ethical and regulatory challenges because it's bigger."

The challenges include the ethical question of whether it is fair to use people's data even when it's de-identified, he adds.

> "WE MIGHT BE FLYING BLIND FOR THE NEXT DECADE... IT'S JUST SOMETHING WE'LL HAVE TO FIGURE OUT."

"Research on data will happen whether or not it's approved by IRBs and academics," Anderson says.

Restricting academic researchers' access to such data could keep them from being able to harness information that could have great social utility, she adds.

"We might be flying blind for the next decade," Anderson says. "It's just something we'll have to figure out."

• What are the biggest ethical challenges with technology?

"Our current framework assumes the researcher and participant have some sort of relationship and they know each other," Anderson says. "In studies involving big data that relationship is not there."

Studies using population data involve a large number of individuals with geographic distance, and people might not be identifiable, she adds.

"That's how the technology creates issues," Anderson says. "The biggest issue now is that we're talking about data that's already out there as opposed to data that one person specifically asks for from another person."

There are good social reasons for using big data, including the potential for better answers from a scientific perspective.

"There's more variation," Anderson says. "But people probably didn't agree to be part of this type of research, and now we have to deal with that."

One simple solution is to cover this possibility in a HIPAA notification: "From time to time, researchers at this institution may review your medical information for research purposes," Spellecy suggests.

Technology continues to evolve, and more complex dilemmas arise.

For instance, now it's possible for multiple data warehouses to link and for researchers to access warehouse networks.

In these cases it might be difficult to let people know on a HIPAA notification form of the possible use and distribution of their data.

"As regional linkages come online, researchers can look at medical data from six or seven academic medical centers," Anderson says. "There are vast troves of data viewed by researchers at this institution and at multiple institutions."

IRBs should ask whether participants would be upset about how their data could be used. A person might have shared information with a family practitioner that now can be used

by researchers from another city or state.

This type of issue should be addressed by the Office of Human Research Protections (OHRP), perhaps through changes to the Common Rule, Anderson says.

"Just as we're thinking of ways to link data, we need to think of ways to involve our communities," she says. "We should learn from each other about what works."

• How do IRBs deal with phenomenon of never-disappearing data?

"What's different now is that everything you do leaves a digital trace," Anderson says. "Every time I go to the doctor now, he enters something into an electronic medical record; every time I buy something online, it leaves some kind of trace online, whether it's Googling or mapping, and that didn't happen before."

There are good and bad things about such readily available data. Many consumers might like having Amazon suggest a book, but they might object to seeing ads about urinary incontinence, she explains.

"IRBs have to stop thinking just in terms of consent and permission," Anderson says. "Instead, we need to think in terms of accountability and transparency."

This requires a multi-pronged approach, Spellecy says.

"With privacy and the Internet, there are generational thoughts on it," he says. "Some people are comfortable with it because they've grown up around technology, and they're comfortable with not having privacy."

For other people, these are troubling issues.

"How do we engage all of these groups when we want to use their medical data?" Spellecy says.

Even as these questions are debated and addressed, public perceptions of privacy on the Web are evolving, Anderson says.

People have been becoming more comfortable with having their data saved and used online, but when the Facebook study was known, they became distrustful, she says.

"What the public wants and expects is changing, and it's what will drive our definition of what respect for persons means and our ways of achieving that," she says.

It would be a problem if people extended their distrust of Facebook's study to medical records research, Spellecy says.

"There could be a chilling effect if people were to find out that their medical records were being used in a way that they feel is inappropriate," he adds. ■

HRPP is ready for growth, including compliance changes

Work smarter, more efficiently

Human research protection programs (HRPPs) are poised for the next level of evolution as today's controversies push research ethics in new directions.

IRBs and HRPP leaders need to look at their programs from a 50,000-foot altitude, suggests **Eric Allen**, CIP, CPIA, associate director of consulting services at HRP Consulting Group, Inc., in New York City. Allen is based in Riverview, FL.

"That's the view you need for a strategic plan," Allen says. "Most research organizations have an overarching strategic plan."

Strategic plans should include oversight and the goal of improving efficiency, he adds.

They could be divided into four main areas: research compliance, institutional compliance, public responsibility, and financial compliance.

"Research protection programs need to work smarter so they can be more efficient," Allen says.

Allen outlines what a HRPP's strategic plan should include and how IRBs might make changes to adapt to 21st century realities.

• Address IRB resources and needs. HRPPs and IRBs need policies and procedures for research oversight with the goal of assessing problems before they grow into something catastrophic, Allen says.

The big issue for more organizations is understaffing, he says.

"A lot of IRBs do their jobs well, while they are understaffed," Allen says. "No one knows how much effort and manpower it takes because it's just 'me and this other person, and we get the job done.'"

Someone needs to let a research

institution's leadership know when resources are a problem because this can contribute to noncompliance issues, he says.

IRBs should make sure all resource issues are identified, managed, and reported to organizational leaders so they can see what needs to be done financially, Allen says.

When an IRB truly needs a funding increase, the argument could be about what it would cost if there is a serious research program violation that results in media reports, legal trouble, or bad publicity.

"If things go south and the institution has a problem that needs to be reported to regulators, how will that affect the organization?" Allen says. "In the worst-case scenario, money could be restricted, and the problem could cost the organization millions of dollars."

Perhaps resources could be shifted and an IRB's workload could be handled within existing infrastructure, Allen says.

"The concept is to make it smarter, to use everyone in the organization to mitigate, manage, and contain the good things and get rid of the bad," he adds.

IRBs also should consider what they're lacking on their board when it comes to handling 21st century studies.

For instance, when regulations were written about IRBs, technology was not an issue. Now it is. So IRBs could have a technology professional on their board to assist with research in the virtual realm, Allen suggests.

"If you don't have an expert, then it's in the best interest of your organization to have a member with some information technology (IT) skills to guide you," he adds.

• **Assess HRPPs' short- and long-term needs.** Research organizations should conduct consistent and routine assessments of their IRBs and HRPPs. They need to know what's going well and what's not working while aiming for efficiency and overall improvement, Allen says.

"Some organizations send surveys to everyone who worked with the HRPP office," he says. "We might think we're doing wonderful things, but the people we're working with have a different point of view, and their perspective is important."

RESEARCH ORGANIZATIONS ALSO NEED TO PLAN FOR MAJOR CHANGES, SUCH AS... MERGING IRBS.

Research organizations also need to plan for major changes, such as starting a medical program or merging IRBs, he says.

If a research institution is adding a new program, the IRB's submission volume will change, and the institution will need a plan for how to ramp up efforts and get new resources in place, Allen explains.

"Someone at the institutional level has to have a strategic plan to show where the organization is going and how the HRPP and IRB fit into institutional goals and what they want to do to improve," he adds.

• **Improve auditing efficiency.** Large research organizations have resources for audits and post-approval monitoring, but this can be a problem for smaller HRPPs, Allen says.

"If I were to look at strategies for doing post-approval monitoring with limited resources, I'd first modify the continuing review form," Allen says. "I'd incorporate additional questions for investigators."

A few questions about the research site's staff, participant withdrawals, study modifications, and changes to the research question could give an IRB insight into any potential compliance problems.

For instance, Allen says, the same questions that might be asked in a post-approval monitoring visit could be included on a continuing review form, including these:

• Where do you keep your files?

• Are your activities consistent with your application?

• Have you changed your password since last year?

• Have you had any changes in study personnel?

• Did you remove any old staff's access to study data?

• Do you have control over the study medications?

• Are you monitoring study medications according to Food and Drug Administration (FDA) guidelines?

• Have you reported all adverse events?

"These are the things you want to evaluate, as well as any problems that come up," Allen says.

An investigator might have made a change that affects risks and benefits, and the IRB could learn of

this through the continuing review form, Allen says.

"A lot of safety monitoring is assuring they're doing everything they said they want to do," Allen says. "Make sure they're following up on the study's confidentiality, monitoring the number of people with access to the files — these are easy questions for investigators to answer."

• **Improve internal communication.** IRBs and HRPPs should communicate with institutional leaders before there's an emergency.

"The message usually is communicated loudest when it's a negative message, but the positive things of having an IRB person who works 80 hours a week doesn't get recognized," Allen says.

IRBs need to work with senior level administrators to form mitigation strategies, figuring out how to prevent problems, he adds.

For example, when there's an institutional expansion or a sudden increase in federal research funding, the IRB and institution should prepare for an influx of money and studies.

"Foresee potential impact changes on your IRB and HRPP and work on them before they erupt," Allen says.

Another example could be when an institution is blindsided by outside criticism of a particular study. This happened a decade ago with some researchers studying HIV/AIDS behavioral interventions to identify ways to reduce transmission among specific high risk groups. Special interest groups targeted some of these studies, basing their objections on the study's focus on risk factors, such as sexual behavior. They claimed the studies were a waste of taxpayer money.

Many institutions and researchers would have stopped their studies in the light of harsh media and national attention. But some kept the lines of communication open with institutional officials and with the public and managed to survive the media storm, Allen recalls.

"Communication is key," he says. ■

Having IC templates can backfire

Over-reliance can lead to unnecessary information

For years now, IRB managers have been developing and using tools, including checklists and templates. The goal is to improve IRB review consistency and to expedite the approval turnaround process. While checklists and tools are useful, they can also be a problem.

"Reliance on tools, such as informed consent templates, can hinder the consent process and impose a number of additional requirements that may not be rooted in human subjects protections," says **Megan Kasimatis Singleton**, JD, MBE, CIP, associate director of human research protections at the University of Pennsylvania in Philadelphia.

Singleton and Tracey Ziolek, MS, CIP, director of human research protections at the University of Pennsylvania spoke about demystifying consent requirements at a recent research community forum co-hosted by several Philadelphia-based institutions and the Office for Human Research Protections (OHRP), held in Philadelphia in October.

"For example, an IRB might provide a consent template as a starting point for researchers to develop their consent forms," Singleton explains. "Templates often can become a source of perceived requirements and some people might rely too much on the document."

This is problematic because one size never fits all for informed consent, she says.

"A consent template is just a tool and not a step-by-step guide that tells you exactly how your consent document needs to be formatted," she adds. "Often there's over-reliance on templates, and this occurs in a way that does not serve subjects best."

Since there are no regulations requiring the use of templates, this is an area where researchers and human research protection programs (HRPPs) could go overboard.

"We found that reliance on this perceived requirement could be a hindrance in consenting creatively and in tailoring the informed consent form to your study," Singleton says.

Singleton and Ziolek discussed various scenarios of when IRBs might be turning recommendations into requirements at the recent OHRP informed consent conference.

"Workshop attendees discussed several hypothetical cases evaluating potential institutional consent requirements," Singleton says.

"In one scenario, an institution committed to reducing the length of consent forms revised their guidance document on consent form development to indicate that all studies with complex study visit schedules must include a procedures table in their consent document," she explains.

"Should that really be a requirement for approving the study, or is that something that could simply be recommended?" Singleton says. "Our argument is that at some point when everything becomes a requirement the goal of the consent document and process may be overlooked."

The workshop attendees agreed that while the use of a table may be helpful in improving subject comprehension, it may be inappropriate to require a table format in order for the consent form to be approved, she says.

"Attendees noted that the requirement of a table may also limit the research team's willingness to consider other creative and potentially more useful options for presenting information such as diagrams, PowerPoint presentations, or a personal study calendar," Singleton says.

Tools, templates, and checklists can be useful, but there are two ways IRBs can prevent them from being abused, Singleton says:

First, when templates and other tools are used they should not be considered equivalent to the regulatory requirements for informed consent. They could be used by IRB staff to check against IRB submissions to make sure they adhere to regulations, but there shouldn't be a focus on exact formatting of the consent document to align with the tools, she says.

> "RELIANCE ON TOOLS, SUCH AS INFORMED CONSENT TEMPLATES, CAN HINDER THE CONSENT PROCESS AND IMPOSE A NUMBER OF ADDITIONAL REQUIREMENTS."

Secondly, IRBs should educate investigators about how to use these as guides, but emphasize that they are not requirements, she says.

"IRBs and researchers should think critically about the potential impact of reliance on standardized tools on the ability to create consent processes and forms that are tailored to the study's target population," Singleton says.

For example, if an IRB hands out its template, saying it is simply a guide for how the consent should be written and then sends a submission back if it doesn't adhere to specific points on the template, then the HRPP is sending the message that informed consent must meet this specific framework to be acceptable, she explains.

"You are creating a requirement by putting this expectation forth and reviewing each consent document against the template," Singleton says.

Researchers who cut and paste template language into their informed consent documents may include information that might not make sense for their study population. It's common for researchers to rely heavily on a template and to believe the template is representative of what the IRB expects to see, rather than tailoring the consent document to their study and target population.

"If you've never written a consent form before, you won't necessarily know what should be in it and what shouldn't be included and the template may often be used as a source of text for the form," Singleton says.

A better approach would be for researchers to think about what their study participants need to know to make an informed decision about study participation and how that information may be best presented to the specific target population.

This should provide the foundation for the development of the IC form, she suggests.

"This is not saying templates are not a good tool," Singleton says. "They can be a great tool. The education around the tool is important, but it's also important for IRBs and institutions to think about whether over-reliance on templates has led us to stray from an approach to consent that is focused on the subjects." ■

IRB self-evaluation form also evaluates HRPP performance

Survey can be adapted for other institutions

IRB board member self-evaluations are crucial for determining how members view their IRB service — and measuring the performance of the HRPP itself. But IRB administrators who are looking for self-evaluation tools may have a hard time deciding where to start, or which issues should be the focus.

Enid Virago, PhD, CIP, CCRP, looked to develop a board member self-evaluation tool as a quality improvement project, and as a means to recruit and retain more IRB board members.

"We have four big IRB panels, and we needed to recruit more members," says Virago, QI/QA program manager at the Office of Research and Innovation at Virginia Commonwealth University in Richmond. "We were trying to figure out how to recruit and keep them, and where their educational deficits were."

Virago partnered with Pennsylvania State University colleague **Joanna Lyons**, RN, DEd, to develop a self-evaluation tool that any IRB office could use. Penn State had been conducting self-evaluations for about five years and developed a survey from a "skeleton" of a form, Lyons says. "Enid and I got together and added more to it," she says. "We have been consistently tweaking it. It's a work in progress." In addition to wanting to gather more information to help in the recruitment, preparation, and retention of effective board members, "this was also driven by AAHRPP requirements for IRB evaluation, and we wanted something more formal than we had before," she says.

Virago and Lyons developed the 12-page "Evaluation of Research Protections Programs and Committee Membership Self-Evaluation" with questions on expectations and experiences of board members. It contains qualitative, open-ended questions as well as statements that can be checked off as applicable, or ranked from "strongly agree" to "strongly disagree." The survey measures satisfactions, challenges, perceptions of IRB service, quality of IRB education, and time needed to conduct reviews. *(For examples of survey questions, see box on page 142.)*

> "EVEN THOUGH LEARNING REGULATIONS... IS A CHALLENGE, IT DOES APPEAR THAT THE MEMBERS REALLY DO WANT TO LEARN."

Virago and Lyons used the survey as a quality improvement effort at their respective institutions and presented a poster of the results at the AAHRPP annual conference in spring of this year. "About 27 people asked for it [the survey] for their own institutions," Virago says. "The survey can be adapted and sections added that would be useful to other IRBs."

Recently, they filled an additional 45 requests for the survey from other institutions. These institutions include medical teaching hospitals, social behavioral research institutions, military, for-profit, and non-profit national and international organizations.

Study results

When Virago and Lyons analyzed the survey data from their institutions, they were surprised by some of the results: Many IRB board members did not feel knowledgeable enough about the federal regulations.

In addition, many board members reported that they did not feel as comfortable with IRB policies and procedures as they thought they should. "The criteria for approval are the most important thing, but the standard operating procedures can muddy the waters, and it's not always a clear distinction between what is a clear [institutional] policy and what is regulatory," Lyons says.

One question, Lyons says, is whether board members are interpreting the approval criteria in

the regulations in a consistent way. "I think the interpretation part is something that IRB members had questions about," she says.

Institutions interpret the regulations in their own ways and develop policies based on the interpretation, Virago says. Each institution can vary in its interpretations. "When someone arrives at VCU from a different institution, they may see that the regulations are nuanced differently than their previous institution," she says.

Finding time to conduct reviews before IRB meetings also proved to be challenging for board members. "It was very clear that time was an issue" for most board members across both institutions, Lyons says.

"One of the other challenges [at Penn State] is in the documentation of reviews in the electronic system," Lyons adds. "Just navigating the system, whether it's a new or different one, can be challenging. We moved over to a new one — there are always challenges in learning how to navigate that."

Lyons and Virago also found another surprise: Some of the things the board members found challenging were the same things that the board members also found to be satisfying.

For example, while board members may not have felt as knowledgeable as they wanted to be on federal regulations, they found enjoyment in the learning process. "In contrast to the challenges, they said that learning about ethics and the regulations are very satisfying," Virago says.

"It is interesting that they thought it was a challenge to learn the regulations, but satisfying to get the understanding," Lyons adds. "Even though learning regulations, guidance, and policy is a challenge, it does appear that members really do want to learn."

Board members gained social satisfaction as well, the data showed. "They liked being an IRB expert in their field, and liked meeting new colleagues," Virago says. "They also enjoyed learning about ethics and studies in other fields."

The board members who reviewed predominately social

Sample questions from the IRB self-evaluation survey

Enid Virago, PhD, CIP, CCRP, and Joanna Lyons, RN, DEd, developed the "Evaluation of Research Protections Programs and Committee Membership Self-Evaluation" to measure IRB member service satisfaction and performance of the HRPP. During the development of the survey, they received assistance from Michelle C. Stickler, DEd, of Virginia Commonwealth University, and Kathleen A. Hay, PhD, Connie M. Manchester, MEd, and Benjamin D. Behler, BS, of Pennsylvania State University.

The survey contains both open-ended questions and statements that can be checked off as applicable, or ranked from "strongly agree" to "strongly disagree." Members are also asked to check off applicable items from lists of challenges and satisfactions. The survey can be accessed through the free, open-source REDCap database.

Open-ended survey questions include the following:

- If you attend IRB meetings, how many hours, on average, do you spend per month in preparation for and follow-up to IRB meetings and other IRB-related activities, outside of the actual IRB meeting itself? Please give the average number of hours spent per month.
- What IRB-related training/education topics would you most like to be provided to you personally and/or to all IRB members?
- Comments you wish to share with the HRPP Protection staff to help improve your ability to function as an IRB member or to improve the effectiveness of the IRB review process.

Ranked satisfaction questions include:

- The amount of time I devote to IRB service is manageable.
- Thoroughness and clarity of presentations I give as a primary or secondary reviewer.
- My ability to apply relevant institutional IRB Written Policies and Procedures.
- Ability to effectively assess when a new member is ready to conduct independent reviews. ■

and behavioral research seemed to view serving on the IRB as a commitment to institutional service and compliance, while board members who predominately reviewed clinical trial research enjoyed the social and professional recognition and satisfaction, she adds.

Institutional improvements

Lyons and Virago are using the evaluation data to gain insight to strengthen education programs for their IRB members. For instance, Lyons and the Penn State IRB asked members for educational suggestions. "We're reinforcing the criteria for approval, and in-meeting education sessions target some of the topics members have mentioned in their evaluations," Lyons says.

VCU is planning to hire an educator, Virago adds.

The IRB also uses targeted education for certain types of studies. For example, if a study involving prisoners is on the meeting agenda, education on the approval of prisoner studies might be presented at the start of the meeting.

"It's targeted so it's a 'just in time' sort of thing and it happens right before they talk about it," Lyons says. "Even though they have their checklists and worksheets, they have this education that they can apply right away."

Tackling the issue of review time has been a little trickier. Both Penn State and VCU were able to get release time from IRB members' departments to ensure that at least some members have adequate time to review protocols. VCU IRB members get a stipend and credit toward tenure for their service, Virago says. "However, pay and credit towards tenure doesn't seem to be a big motivator for the biomedical reviewers, and oftentimes they are too busy to take release time," she says.

In the future, Virago and Lyons hope to share the survey with more IRB programs and update it based on user feedback. "When we send it to people, we ask them to send us comments if they use it," Virago says. "We consider it a living document, and we'd like to see any changes so we can continue to make it better. If they want help writing questions, they can give us a buzz and we can help." ■

Here's a change we know you'll like: From now on, there is no more having to wait until the end of a 6-month semester or calendar year to earn your continuing education credits or to get your credit letter.

Log on to www.cmecity.com to complete a post-test and brief evaluation after each issue. Once the completed evaluation is received, a credit letter is e-mailed to you instantly.

If you have any questions, please call us at (800) 688-2421, or outside the U.S. at (404) 262-5476. You can also email us at: customerservice@ahcmedia.com.

Let us know what you think of *IRB Advisor*'s new layout. Send your comments and questions to jill.drachenberg@ahcmedia.com. We want to hear what you think of the new masthead, logo, and three-column format.

COMING IN FUTURE MONTHS

- Recruitment and retention ethical challenges
- Improve management of subjects complaints
- OHRP's new risks guidance analyzed
- The challenges of Right to Try laws

IRB ADVISOR

CNE/CME INSTRUCTIONS

To earn credit for this activity, please follow these instructions:
1. Read and study the activity, using the provided references for further research.

2. Scan the QR code below or log on to www.cmecity.com to take a post-test; tests are taken after each issue. First-time users will have to register on the site using the 8-digit subscriber number printed on their mailing label, invoice or renewal notice.

3. Pass the online tests with a score of 100%; you will be allowed to answer the questions as many times as needed to achieve a score of 100%.

4. After successfully completing the test, your browser will be automatically directed to the activity evaluation form, which you will submit online.

5. Once the completed evaluation is received, a credit letter will be e-mailed to you instantly.

CNE/CME QUESTIONS

1. In its new draft guidance on disclosing reasonably foreseeable risks of research in standard of care studies, OHRP considers reasonably foreseeable risks to include the different risks associated with the standards of care being evaluated in the research.

A. True
B. False

2. How have population-based studies changed in the era of 'big data?'

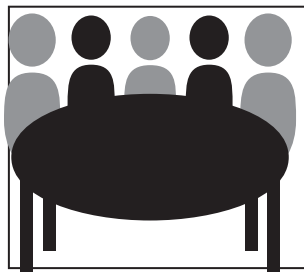
A. Information about individuals online leaves traces — never disappearing
B. Data now is shared with multiple institutions and researchers have less control and information on its collection
C. IRBs need to think of new ways to meet "respect for person" requirements because informed consent doesn't work in big data studies
D. All of the above

3. Smaller IRBs can modify their continuing review form by asking additional questions that will help with post-approval monitoring. Which of the following is not a useful question to ask on the continuing review form?

A. Are your activities consistent with your application?
B. Would you participate in an IRB satisfaction survey?
C. Have you changed your password since last year?
D. Have you had any changes in study personnel?

4. Why might over-reliance on IRB informed consent documents and templates hinder the goal of improving human research program protection?

A. IRB staff will forget processes and steps when reviewing submissions because of their over-reliance on tools
B. Investigators will ignore the forms and sometimes do an even less thorough job of completing their submissions
C. Reliance on tools can impose a number of additional requirements that may not be rooted in human subjects protections
D. None of the above



IRB ADVISOR

2014 Index

When looking for information on a specific topic, back issues of IRB Advisor may be useful. If you haven't activated your online subscription yet so that you can view back issues, go to www.ahcmedia.com. On the right side of the page, click on "Access Your Newsletters." You will need your subscriber number from your mailing label. Or contact our customer service department at P.O. Box 105109, Atlanta, GA 30348. Phone: (800) 688-2421 or (404) 262-5476. Fax: (800) 284-3291. E-mail: customerservice@ahcmedia.com.