IRB ADVISOR

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INSIDE

Informed consent flexibility on fed side results in creative IC

Teach-back, other strategies used

In recent years, IRBs have witnessed federal regulators becoming more flexible in applying regulations regarding informed consent (IC) — a shift resulting in more creative and practical IC methods, including electronic, short form, and video consent. Changes are necessary as research evolves and informed consent becomes necessary in new scenarios.

For example, regulators are moving toward requiring informed consent for studies involving genetic screenings and tissue samples.

Recently, lawsuits targeted states over the perceived lack of IC when newborn tissue was retained for research after routine screening at birth, notes **Erin Rothwell**, PhD, associate professor of research in the division of medical ethics and humanities in the college of nursing at the University of Utah in Salt Lake City.

"Two states were sued successfully by parents who felt like they weren't properly informed about leftover screening samples," Rothwell explains.

"What I've found is that we're moving toward a trend with the advance notice of proposed rulemaking where any type of sample is going to be considered human subjects research," she adds. "So we're interested in how you engage within that clinical encounter and in a population setting, where you're trying to consent hundreds of thousands of people."

> "WHAT I'VE FOUND IS THAT WE'RE MOVING TOWARD A TREND WITH THE [ANPRM] WHERE ANY TYPE OF SAMPLE IS GOING TO BE CONSIDERED HUMAN SUBJECTS RESEARCH."

One potential IC solution is to provide electronic informed consent, along with video and written materials, Rothwell says. *(See story on IC for studies using genetic tissue, page 87.)*

IRBs and researchers have focused

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in recent years on evidence-based ways of improving the informed consent process, including using the teach-back method. One innovative approach is the Valid Informed Consent Education (VoICE) project, which was started to provide researchers and others with training on how to obtain informed consent, says **Elizabeth A. Bankert**, MA, director of the IRB office at Dartmouth College in Hanover, NH.

"We found that there weren't a lot of educational programs out there to teach people how to obtain consent," Bankert says. "It was usually just observing somebody else give consent and then doing it yourself with very little formal education."

"VoICE was created to fill this gap, and it soon will be available online," Bankert says. *(See story about VoICE, page 88.)*

The IC shift also encourages IRBs to waive informed consent when appropriate.

"More and more institutions are looking at, for example, minimum risk research and whether they're still requiring an informed consent process," notes **Ada Sue Selwitz**, MA, director of the office of research integrity at the University of Kentucky in Lexington.

"Now institutions are beginning to waive documentation as the standard," Selwitz adds. "They've unchecked the box, saying it's minimal risk, and you may still be required to get informed consent, but you don't have to document."

As a result, an increasing number of IRBs nationwide are beginning to feel more comfortable using both the waiver of informed consent and waiver of documentation of informed consent, she explains.

The trend — at least for IC in sociobehavioral studies — has shifted from requiring informed consent every time there's a face-to-face contact with a participant to finding alternatives to formalized consent, she adds.

Examples of when IC might be less formal include research involving discussion groups, surveys, and interviews for sociobehavioral-anthropological studies.

"Also there's been considerable more use of the short form," Selwitz says. "In the regulations for years we've had the option of using the short form with a witness, and traditionally it's only been used in individuals who were non-English speakers."

That's changing: Now people are using the short form in different ways, she adds.

For example, short forms can be used for research participants with literacy issues or with disabilities such as sight or hearing impairments, that make the traditional informed consent process challenging.

Short forms are amenable to IC in those cases, says **Susan Rose**, executive director of the Office for the Protection of Research Subjects at the University of Southern California in Los Angeles. Rose is also on the editorial board of *IRB Advisor*.

"First of all, it's allowable, which is most important," Rose says, referring to the Food and Drug Administration's (FDA's) Informed Consent Regulations/ Guidance (http://www.fda.gov/RegulatoryInformation/Guidances/ucm126431.htm).

Using a one-page IC form is a simpler way to explain research to participants, Rose adds.

But the page is only one part of the IC process, and the same is true for participants with limitations and disabilities, she notes.

"With blind subjects we provide oral informed consent; with deaf ones, we could use sign language,"

Rose explains. "When participants have different languages, you can use a short form process and use telephone translation services, but you'd need to document that."

In the case of illiterate participants, there could be one person who provides oral informed consent, and another present to witness it, Rose says.

"You can use pictures and cartoons for informed consent, and those work best, but are expensive and you can't mandate their use for every study," she adds. ■

Strategies for providing IC to very large subject pools

Newborn blood spot screening forces issue

Newborn blood sample screening has been going on for decades, but ethical considerations have evolved in recent years, and this is changing research informed consent. For instance, the public has learned that researchers sometimes use the samples for studies, and some parents are alarmed at the collection of genetic material as whole-genome sequencing has moved from science fiction to fact.

In the 52 years since the publication of a test using dried blood spots to screen children for phenylketonuria (PKU), nearly every U.S. newborn has undergone the screening.[1]

The Newborn Screening Saves Lives Reauthorization Act of 2014, which became public law on Dec. 18, 2014, makes this important change: "...requires federally funded research on newborn dried blood spots to be considered research on human subjects (which requires the informed consent of the subject), and eliminates the ability of an institutional review board to waive informed consent requirements for research on newborn dried blood spots."[2]

Now the question for IRBs and others is how to retain newborn screening and make even better public health use — including research — of the collected samples while obtaining informed consent.

Ethical considerations are even more topical in light of recent lawsuits where parents sued the Texas Department of State Health Services and Texas A&M University System for failing to ask parents for permission to store and possibly use their newborns' blood samples. As a result of the lawsuit, filed by the Texas Civil Rights Project, Texas health authorities destroyed more than five million blood samples taken from babies without parental consent. Going forward, the state needed to obtain parental consent before the samples could be collected, stored, and used for research.[3]

A similar lawsuit in Minnesota also succeeded. The chief issue was the ownership of newborn DNA and parental informed consent, according to the ACLU.[4]

The lawsuits and informed consent changes regarding tissue samples are what prompted some researchers to study the effectiveness of a simplified, electronic informed consent process for parents of newborns.

"Four million babies undergo screening in the U.S. without informed consent, with the exception of a few states," says **Erin Rothwell**, PhD, associate professor of research in the division of medical ethics and humanities, college of nursing at the University of Utah in Salt Lake City.

"We wanted to do a pilot study within an ongoing randomized control trial about the role of electronic consent at one Utah site," Rothwell adds.[5]

The idea was to see if electronic informed consent, which can easily be administered to large numbers of participants, could work ethically and effectively in a research setting.

Rothwell and co-investigators assessed an electronic informed consent model in a pilot study that randomly assigned participants to either an electronic IC or a simplified paper-based consent group.[5]

"We'd have people watch a video about newborn screening and genetics and then assess their attitude after they've had their baby, to see if it negatively affected the program," Rothwell says.

"We found that the video was quite effective as a consent process when compared with the simplified paper-based consent process," Rothwell notes.

But investigators also found that in some cases, a hybrid approach to IC that includes electronic and paper-based consent would work best.[5]

"From our pilot data, we submitted a [research grant request] to the National Institutes of Health to test electronic informed consent in three different Michigan hospitals," Rothwell says. "We hope to streamline the electronic consent process, and we're very excited about it."

Their proposed study was still

pending as of late June 2015.

The goal is to demonstrate to researchers, IRBs, and sponsors an IC model that could work both ethically and pragmatically with biospecimen collection, she adds.

"Consent does take time and a lot of resources," Rothwell says. "And with studies involving biospecimens, it's a very low risk; there is no known case where there has been actual harm to an individual for using their leftover tissue."

With the IC requirement in the newborn screening act, and with the very real possibility that the Common Rule also will be changed to expand the definition of human subjects, some kind of streamlined IC process is necessary, she adds.

"The big thing we're trying to do is streamline the consent process and figure out what is the adequate amount of information someone needs to know to make an informed decision of whether to participate or not," Rothwell says. "That's what sparked my interest in it: How can we engage people and capture attention so that if they find out a researcher is using their blood sample, they'll know what's going on?"

One potential solution is the use of a five-minute video based on a simplified consent form.

"The people who watch it have to decide whether or not they want to agree," Rothwell says. "For a potential randomized control trial in the state of Michigan, we'll include the video, which can be watched on someone's mobile phone."

Once they see the video, participants can sign the electronic IC.

Michigan already has in place, in most hospitals, an informed consent process for newborn blood screening. "But they're only getting a 60% uptake rate, which is why we're focusing on informed consent within the clinical and research setting," Rothwell explains.

The rate is lower than desired because new moms often leave the hospital before they can be asked to sign the IC form, and there isn't enough manpower at hospitals to track them down once they leave, she adds.

"Clinical staff has to give new parents a brochure and have to return to them to have them sign a form," Rothwell says. "With the competing health demands of a new baby, that can be difficult."

The proportion of parents who refuse to allow their newborn's sample to be used in research is fairly low, but many more parents are simply lost to follow-up. "We're missing a big chunk of the population, and we're trying to figure out how to improve the consent process," she says.

Also, researchers are considering trying different ways to reach people for IC, including using emails and text messages.

"We've reached a point where a lot of our population has smartphones," Rothwell notes.

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VoICE Project fills education gap in informed consent process

Teaching teach-back works

Research institutions should make certain the responsibility for a successful informed consent (IC) process is primarily that of the researcher and not the potential participant. One way to do this is to educate researchers and others in human subjects research protection on successful IC strategies.

Simply asking participants, "Do you understand?" is not adequate, says **Elizabeth A. Bankert**, MA, director of the IRB office at Dartmouth College in Hanover, NH.

"About 10 to 15 years ago we developed an informed consent feedback tool for research subjects that simply lists the items you should understand before enrolling in a study," Bankert says. "When we implemented the tool, we had a few questions at the end about how useful was the tool."

Participants in the pilot study commonly replied that if they hadn't been told what they needed to know, they wouldn't have known what questions to ask, she notes.

"I use this as an example: When you're getting a new mortgage, you don't know what questions to ask," Bankert says. "So we remind people that research participants aren't as embedded in the whole research community as we are."

The Dartmouth IRB now educates researchers and research staff in a two-hour program, called the Valid Informed Consent Education Program (VoICE), on why and how to obtain informed consent.

"The first part explains the importance of obtaining consent, acknowledging how difficult it is, especially with time constraints in the healthcare setting," Bankert says. "We spend time on the elements of informed consent for research purposes, and we spend quite a bit of time on health literacy."

The program also teaches researchers how to do the teach-back method of IC, ending with having them practice teach-back.

"We found in our pilot program that it takes practice," Bankert says. "People are used to saying, 'Do you understand?' or 'Do you have questions?' and that's not what we want."

Instead, researchers conducting IC should ask open-ended questions, such as, "If your sister calls you tonight to ask about the research study, how are you going to describe it to her?" Bankert explains.

The project showed that researchers can increase their knowledge of teach-back questions and reduce the number of closed-ended questions they've been using habitually, she adds.

The pilot study's findings showed that people learned how to ask more questions like, "Explain to me in your own words what the risks are?" Bankert says.

"What we aim to do is show that it increases comprehension in the research setting," she adds. "It has been shown to improve comprehension in the clinical setting, and we're only transferring this technique to a different setting."

Bankert suggests IRBs and research institutions can take the following steps to improve IC process education:

• Research teach-back online. There are a number of studies published about teach-back, and a number of institutions have published online information about the method.

For example, tools and videos are available at the Always Use Teach-Back website (www.teachbacktraining.org).

One tool is the one-page "10 Elements of Competence for Using Teach-back Effectively." Among its suggestions are these three:

- Use a caring tone of voice and attitude.

- Use non-shaming, open-ended questions.

- Use reader-friendly print materials to support learning.

Another helpful Web page is about coaching to using teach-back (http://www.teachbacktraining.org/coaching-to-always-use-teach-back).

• Help researchers develop new habits. Most people providing informed consent in research have developed habits and a method they use repeatedly. The goal of VoICE was to help them change their habits to a more effective IC method, according to Bankert.

For example, when teaching the teach-back method, instructors will produce better results among researcher attendees if they encourage them to use the new habit and to observe others using the method, according to the Always Use Teach-back coaching tips.

Instructors can use active and reflective listening and ask these questions:

- "What worries you about using teach-back?"

- "How did using teach-back with your patient make you feel?"

- "Tell me more about…"

"Research coordinators and team members are definitely looking for help in improving the dialogue and process of informed consent," Bankert says. "They realize how difficult it is and appreciate it when we acknowledge that it's difficult."

Empathy for their challenges in conducting IC also helps build rapport and is far more helpful in improving the IC process than for IRBs to wordsmith an IC form, she notes.

• Use the IC document's headers as a guide. "What we find is the consent form is a useful document that individuals can use as a reference tool," Bankert says. "It's a good reference as you go through the process, but it's not the only piece of obtaining informed consent; it's just one part of it."

By looking at the IC form's headers, a researcher can steer the teach-back IC in direction of the most important facets of the study, Bankert says.

"You discuss the main sections of information and ask teach-back questions for each of these," she explains. "I've had some research coordinators ask a teach-back question after each section and then not go on until there is good comprehension."

• Incorporate the main elements

of IC in the class. "We cover the elements of informed consent," Bankert says. *(See the short version of IC elements, below.)*

"We explain that every research study is different," she adds. "The role of the IRB and research team moving forward should be to try to figure out the key components that people should understand for any research study in particular."

For example, if they have a high-risk study, the question for researchers to ask themselves might be, "Is that toxicity far beyond what subjects might be exposed to in standard of care treatment?"

Whatever is different or challenging about a particular study and how these tie to the elements of IC should be the researcher's focus during the IC process, she says.

"What are the key elements of each particular study?" Bankert says. "This needs to be discussed within the research team."

• **Give researchers strategies for determining comprehension.** If a research subject's answers to open-ended questions are inaccurate or not very detailed, then it would suggest the person doesn't fully understand the study and more informed consent is necessary. In these cases, the researcher can say, "I didn't explain it correctly. Let me explain it again," Bankert suggests.

Or they can say, "Let's spend a little more time on this because it's really important," she adds.

This works better than post-IC tests because it is a more dynamic way of assessing a person's level of comprehension, she says. "You're not supposed to move on to the next topic until you're comfortable with the comprehension level of the topic at hand," Bankert says. ■

Here's a short version of the criteria for approval

Criteria cover eight key points

Title 45, part 46.111 of the U.S. Department of Health and Human Services' Protection of Human Subjects, revised in 2009, contains a very short, but important list of criteria for IRB approval of research.

The following are included in the criteria:

• Minimize risks to subjects by using sound research design that does not unnecessarily expose subjects to risk.

• Evaluate risks and benefits to see that risks to subjects are reasonable in relation to anticipated benefits.

• Select subjects equitably and be particularly cognizant of research issues related to involving vulnerable populations.

• Seek informed consent from each prospective subject or the subject's legally authorized representative.

• Document informed consent.

• Monitor the data collected, as appropriate, to ensure subjects' safety.

• Protect the privacy of subjects and maintain data confidentiality, when appropriate.

• Provide additional safeguards when some or all of the subjects are likely to be vulnerable to coercion or undue influence. ■

BEST PRACTICES *SPOTLIGHT*

Using QI to improve electronic and other systems or processes

Here's how to best assess needs

Many IRBs have had quality improvement processes and electronic IRB systems in place for a number of years now, but are they working optimally?

Just having a quality improvement (QI) program in place is not the same as having continuous quality improvement or having a system that regularly identifies issues and prevents problems. What human research protection programs (HRPPs) and IRBs might need is a quality improvement project for their QI and other processes and workflow, according to **Candice Yekel**, MS, associate vice president for research, and **Sara Horn**, CIP, assistant director of the Office for Research Protections at Pennsylvania State University in University Park.

"We've had an official QI program for at least six or eight years, and we've been building it over the years to do

a number of things, including post-approval reviews and quality checks," Yekel notes.

"Most recently, QI activities helped us to recognize that our system hadn't been meeting the program's needs," Yekel adds.

"We either needed to enhance the homegrown system and put a lot of resources into it, or we needed to buy a commercially available product," she adds. "We thought figuring out how to put in an electronic system was a QI activity, and we put together a task force to determine whether to use the homegrown system or purchase a new one."

There were two major deficiencies in the old electronic system, Horn says.

"It was great for managing protocols in our office, but it had no meeting management functionality," she explains. "So we had to use other mechanisms with anything that had to go to the full board."

For example, there were no mechanisms for handling unanticipated problems, noncompliance, and other things that are now referred to as reportable new information, Horn says.

Although everyone agreed the electronic system needed to be improved, it wasn't certain whether the improvement would involve replacing the existing electronic system with something new or patching and repairing problems, but retaining the existing system. So they put together a task force to help make this decision, Yekel explains.

When the existing system was created, there were few commercially available options that fit in with the institution's HRPP needs, she adds.

"Our mindset at the time was that we could build our own system, but we learned very quickly that it costs a lot of money to build a system and maintain it," Yekel says. "And we had very limited information technology [IT] resources."

This resulted in IRB analysts doing some of the IT work, which was unsustainable as a solution, she notes.

"We were building this system for a long time, and it was good, but it wasn't good enough," Yekel says.

The task force, along with institutional leadership, helped them reach the decision to purchase a new system and start over.

"Once we made the decision to purchase a commercial product, we felt it would be an excellent time to review our HRPP process to make sure we had maximum efficiency," Yekel says.

This is where the second phase of a quality improvement process began: "We evaluated all IRB staff and processes and looked for where there were inefficiencies and did some process mapping."

"We were charged by the vice president for research at the time to make this process transformational, and so we embraced that process of transformation," Yekel says. "We made significant changes in how we thought about work, monitoring ourselves, and continuous quality improvement."

The changes resulted in shorter review timelines and a more transparent and streamlined IRB process, Yekel says.

"Investigators know where their submission is in the process," she adds. "They can see real data on how the IRB and IRB staff are performing."

The new system also makes it easier to collect QI data, such as the following data points:

- How long does it take to get an initial response from the IRB?
- How long are investigators making revisions to the protocol?

Part of the transformation was a philosophical change, Yekel says. The legacy system was designed to ask hundreds of questions with each answer branching off into a new batch of questions. "It was like a tree that keeps expanding," she says.

The problem was that the additional questions did not result in better IRB submissions or make the process better, she adds.

"We needed the right information, so we adopted a HRPP toolkit that included a series of quality measures and procedures that were compliant with federal regulations and with the standards of AAHRPP," she says.

The toolkit includes standard operating procedures (SOPs), worksheets, checklists for IRB analysts, and workflow diagrams, Horn says.

"IRB analysts and members can use those workflow diagrams to help them understand how a review occurs and how a submission moves through the review process," Horn explains. "The electronic system and the review process mirror the workflow in the toolkit."

The tools were incorporated into the software so the electronic system would be able to collect and analyze the most useful data. The tools also were used by IRB staff prior to use of the electronic system to help them become accustomed to the new workflows, Horn says. *(See story on how to overhaul an IRB's processes, page 92.)*

"Previously, we had our own SOPs, checklists, and worksheets for IRB review," she explains. "Then think of it as we threw all of those out the window and started over; that's what we did."

They created a responsibility matrix team with outlined responsibilities for individual team members. "That team was responsible for evaluating the HRPP toolkit document and determining where we might make some small tweaks," Horn says. "We did a lot of work on those documents before we began to use them." ■

Overhauling processes is a major HRPP challenge

Here are some steps to take

IRBs have accumulated a lot of responsibilities and processes over the years, and some of it is not necessary or not really part of the IRB's role, experts say.

By overhauling IRB processes and using electronic data in a focused quality improvement initiative, an IRB can make its operations more efficient and faster, according to **Candice Yekel**, MS, associate vice president for research in the Office for Research Protections at Pennsylvania State University in University Park.

"Our IRB was going well beyond what was required in the regulations — mission creep," Yekel says.

"We wanted to peel back and say, 'What is the IRB supposed to do?'" she adds. "And we want to do those things very well, so it might be a good idea to rethink how we are doing things."

This type of project is bigger than the IRB, notes **Sara Horn**, CIP, assistant director in the Office for Research Protections at Penn State.

For Penn State, the project spans all other compliance committees, as well as the IRB. These include the institutional biosafety, animal care and use committees, and others.

Yekel and Horn offer these suggested steps for overhauling processes and compliance mission:

1. Evaluate staff structure and workflow.

The Penn State HRPP enlisted help from consultants and began the process of evaluating its staff structure and its efficiency.

"We realized our staff structure and way we processed submissions related to staff structure wasn't the most efficient system," Horn says. "Researchers were experiencing inconsistency from one review to the next, and we wanted to put a process in place that ensured some consistency."

As the IRB reviewed its staff structure, they realized that some roles could be restructured, Horn adds.

"We didn't have a true director of our IRB program at the time and we had gone through a lot of changes, so we first acknowledged that the IRB needed its own leadership," Horn explains.

Previous to the transition, there was a director who was responsible for many compliance areas. The change would mean the IRB would have its own director, Yekel says. "It's better to have someone in that position who knows what's going on and is managing the program right there in the trenches."

In Horn's role as assistant director of the Office for Research Protections, she manages the day-to-day IRB program activities and serves as a member on both IRBs at the University Park location.

"Through the re-evaluation of our staff and their qualifications, we were able to restructure our staff into two different teams," Horn explains.

Each team consists of a senior IRB program leader and IRB analysts.

"Previously, we had what we called team leaders, but they didn't have a vested interest in leadership or the overall direction of the program," Horn says. "This formalized that position and created more of a career ladder within the program."

Team leaders were the IRB employees who had the most seniority and the greatest depth of knowledge, Yekel says.

In their new roles, they have a vested interest in making sure the program is running smoothly and they are responsible for the outcomes and performance of IRB reviews, she adds.

Another staff change was to shift the IT responsibility from the IRB analysts, who had been handling much of the IRB software issues, and — instead — use IT staff to maintain the electronic system, Yekel says.

"We also have business analysts to do a lot of the heavy lifting, such as gathering information about the needs of the IRB and developing solutions for the electronic system that meet those needs," she adds. "Now, IRB analysts are no longer involved in building or maintaining an electronic system and they are focused on IRB-related work."

2. Budget for maintenance and repairs.

One of the failures of the HRPP's previous electronic system was that the program didn't have dedicated staff to handle electronic management of the system, Yekel says. "We had some IT people, but staffing was limited; now we have an IT workforce to maintain and customize the system."

This change was a big shift, she adds.

3. Drill processes down to what's necessary and in the regulations.

"We have worksheets that help the staff look for things required by the regulations in the informed consent forms," Horn says. "One of our big changes involves the mentality surrounding the review; our analyst in the past might have had a long list of specific statements to add to the

informed consent form."

But the regulations do not require the insertion of specific language in the consent form, Horn adds.

"So now we go back to investigators and say, 'What are you doing, and how would you like to have this put in the informed consent?" Horn says. "We've gotten rid of old required phrases and let investigators use their own words."

4. Create a more efficient IRB meeting.

"We've made some changes to our IRB meetings," Horn says. "One effort was getting IRB members to focus on the criteria for review when reviewing a study."

Previously, the IRB office provided support materials for IRB members, and they'd gather to talk about regulations, she notes.

As part of the change, Horn would display HRPP regulations on a large screen for IRB members to view while they discuss a protocol. "We discuss each regulation, one by one, to see if the entire board feels that a particular regulation was met or was not met," she says. "We literally have a very clear and transparent discussion about whether something is meeting criteria outlined in the regulations."

While Horn doesn't display the regulations at every meeting now, she still brings the criteria for review up on the screen and asks IRB members to make certain the criteria are met.

"IRBs can get hung up on the minutia and forget that a protocol needs to meet the criteria for approval, and making that determination should be the most important thing they do," Yekel notes.

"Anytime the IRB requests a modification required for approval, we have them indicate the review criteria that is not being met and the exact change that needs to be made," Horn says. "Then we communicate with the investigator, saying, 'We want you to make this change and here's why.'"

This transparency alone has produced a dramatic change, Horn notes.

"I've seen a dramatic change in the content of the discussions of the IRB, and they are certainly more focused on real risks to participants and more focused on those regulatory criteria for approval," Horn adds.

Another change was to have an IRB analyst take minutes during the IRB meeting instead of recording the meeting, and then having a staff assistant transcribe minutes later, Horn adds.

"IRB analysts have a lot of knowledge about the protocol, so it makes sense to have them take minutes," she explains. "They attend meetings for the protocols they coordinate; they're taking minutes and helping with the meeting should the IRB need it."

The IRB meetings also achieved greater efficiency by switching from a hybrid electronic-paper process to a fully electronic review process, she adds. ■

"Big data" is at every IRB's fingertips — but can you use it?

You need to know what you don't know

Research institutions increasingly are investing in electronic systems that have the capability of collecting and storing big data. The information can be used to improve IRB processes, identify systemic flaws or problems before they develop into a crisis, and to run a HRPP as efficiently as a major airport's air traffic control.

But it takes more than software to achieve these outcomes. IRBs need to know how to use and obtain the most benefit from their electronic data-collecting systems.

"If you have electronic data mining tools, then you can use those tools to assess workflow applications and to make decisions about resource applications," says **Judith Marie Birk**, JD, director at the University of Michigan Medical School Institutional Review Board (IRBMED) in Ann Arbor. IRBMED recently purchased a new electronic solution that provides an improved look at an IRB's big picture.[1]

"When you have a robust tool, it can tell you a story about your metrics and also allow you to drill down very systematically," Birk says.

For example, electronic data mining tools with internally consistent data analytics have the following capabilities:

- Look at metrics of studies reviewed by the full board or at an expedited review,
- drill down to department level to see which institutional areas require more resources,
- measure turnaround time at each step of the protocol submission process with real-time reporting and data visualization capability[1],
- assess workflow issues, and
- examine resource allocation priorities.

"Everybody has data, but it's hard to work with that data because reports tend to be one-off reports," Birk says. "People will run a report today and then run it again in two weeks and compare."

IRBMED has used its data technology when recruiting additional IRB reviewers from University of Michigan departments that have high research volume, she notes.

"It's been beneficial to us to show a department why we need more members of the IRB," she says. "We can say to the chairman of the department, 'We would like you to give us another reviewer because you're high volume.'"

If the chair answers that the IRB already received another member from that department, it's time to pull out the data to show how much volume had increased in the previous 12 months, she adds.

"We can go across time and show volume and the type of submissions made to the IRB, year by year," Birk says. "We can indicate the number of reviews we've assigned to each expert in a particular department and demonstrate that while we have only two reviewers, we really need four because they're overloaded."

Having robust data has given more credibility to the IRB's request for more expert assistance. "We could have asked for more reviewers before, but it would have taken 10 times longer."

With big data, the IRB has a global view of where workflow blocks occur and why.

A more robust tool can be fully integrated with IRB processes and provide instant comparisons at any set time periods. It also will provide user-friendly and interactive dashboards with graphic designs that make it easier to understand data trends.

"What our new system will do is let you set the parameters and then define how you want it broken down, whether it's by month, years, or weeks," Birk explains. "You can make a process change and then measure to look at its success."

It's also important to make certain the data technology ensures data validity, she says. The institution can do this by developing a set of reporting queries that electronically interrogate the IRB and human resources systems daily. This safeguards against human error and bias.[1]

Birk provides the following strategies for using data technology optimally:

• Determine your IRB's priorities and analyze data related to the most important process first. "Every IRB is conscious of turnaround time," Birk notes. "We want to optimize our workflows and have a quick turnaround for investigators; we want to be efficient and get materials back in the hands of investigators as soon as possible."

An IRB's data technology should have the capability of letting an IRB office examine the various steps in the process of protocol review so the review process can be optimized, she adds.

"One thing that's been historically difficult to examine is the amount of time a study spends with the study team and IRB office and reviewers," Birk says. "There typically are three big components, and there can be the fourth component for clinical research studies of any additional committees that have to review a study, like a radiation safety committee or research pharmacy."

A data technology tool can take the application from the time it starts in the electronic system and examine it across its lifespan with ease. The IRB can then assign metrics and use the collected information to drive workflow and other decisions related to optimizing efficiency, she adds.

• Use data technology to address workflow and personnel issues. When the IRB office discovers a workflow problem identified in data, it can be discussed with staff and used to develop process improvements. "There might be perceptions that are not accurate, and this helps to eliminate perceptions," Birk says.

Also, big data can highlight systemic or overall process problems, such as a work system that uses staff resources inefficiently.

"IRBs receive many types of submissions, including initial, adverse events, continuing review, and some IRBs have individuals do everything from soup to nuts, while others have a team approach," Birk explains.

Using data technology, an IRB can assess on any particular week whether the current process works best. For example, an IRB might identify a particular staff member whose timeliness has slowed during a week. The person appears to be overloaded, Birk says.

With this real-time data, the IRB can shift some work to another member of the IRB staff and expedite that week's review process, she adds.

"You can watch this on a daily basis as work comes in, and you can assess and balance by staff expertise, turnaround time, and workload," she says. "It gives you more flexibility in the office."

With the right data markers, it's possible to identify these kind of work logjams and quickly correct them.

"For this to work, all IRB work would need to be assigned by individual with an automatic time stamp associated with the work," Birk says. "This is so you can measure when the clock starts and the volume."

And the data warehouse would need to be refreshed nightly so the IRB always is working off one-day-old data, she adds.

• Be detail-oriented when selecting markers. An IRB could think of the data markers as being in two different groups. The first group entails the research institution's basic story — the

transparent information it wants the world to see — and these would be collected and produced in canned reports, Birk explains.

"What do you want to tell the world about what we do?" she says.

These reports could include descriptions of each research entity's portfolio of research. Detailed data in each report would describe how many studies went to the full board, the review turnaround time, and expedited review, Birk says.

"Those are the standard metrics that tell the story," she says. "If an institutional official wants to know information, or if your institution belongs to a consortium that wants to know what they look like, these are the metrics."

The second group includes data markers selected by the IRB to improve its own processes and quality. "You determine what's in your data warehouse based on what questions you want answered," Birk says.

"Right now, we have a project to look at streamlining one of our review models within the office, and we're breaking that down into each of its component steps," Birk explains. "We're starting with the submission of the project to the office and how it is assigned to a reviewer and the workflow associated with that."

The goal is to reduce the turnaround time, so the tool includes markers that will help answer that question, she adds.

"We actually asked to have the data warehouse refreshed recently to get some historical and baseline data so we could make a change to the workflow and have a benchmark for it," Birk says.

The markers are very specific to any question the IRB wants answered and typically requires multiple steps. For example, an institution might have a department that has high volume research. The IRB would want to know answers to these questions:

- When do they submit studies and are there any seasonal or monthly trends?
- Why do they submit the most studies in a specific period of time?
- Are many of these studies from students or medical fellows?

"Maybe most studies are submitted in September, so the department needs more IRB reviewers at that time," Birk says. "Or maybe they're high volume all the time, and the IRB needs more faculty reviewers from the department to do the work."

These are the kinds of assessments the IRB can do with the correct markers, she says.

• Check the operations dashboard to make daily or weekly tweaks and changes. Dashboards are visually appealing ways to describe data. They can use color theory and graphical concision to give the IRB a quick visual understanding of trends and patterns.[1]

They can use bar graphs, line graphs, and other graphics. For IRBMED, viewers, depending on their security level, can drill into any area of the chart and it would provide a consistent narrative. For example, one graphic shows the staff reviewer turnaround times broken down into five different teams and results for five consecutive years.[1]

"We've set up the dashboard to produce reports at a click of the button; we can download reports and set them up to be produced with a visual — a table, or graph, or chart," Birk says. "Then you can access raw data behind that and it can be exported to Excel."

The standard dashboard provides a look at the things an IRB wants to know in an ongoing and flexible way. It also can highlight outliers and give details that help uncover the root cause of a problem, such as a processing delay.[1]

Across time, IRBs can ask different questions and watch for long-term trends and workflow patterns. "Having a benchmark is very important; knowing where you're coming from and then tracking it going forward," Birk adds.

REFERENCE

1. Smith C, Ramani V, Birk J. Using visual and data technology to inform IRB operations. Presented at the PRIM&R Advancing Ethical Research Conference, held Dec. 5-7, 2014, in Baltimore, MD. ■

COMING IN FUTURE MONTHS

- Guidance to improve Phase 1 cancer research informed consent
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IRB ADVISOR

CNE/CME INSTRUCTIONS

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

CNE/CME QUESTIONS

1. The Newborn Screening Saves Lives Reauthorization Act of 2014 makes which change to research on newborn dried blood spots?

A. Such research should be considered research on human subjects, which requires the informed consent of the subject
B. Research involving newborn dried blood spots can be conducted so long as a nurse told the parents that the collection of the samples is a routine screening test and the nurse obtains a signature on a clinical consent form
C. The reauthorization act prohibits all research on the newborn dried blood samples
D. None of the above

2. In the teach-back tool titled, "10 Elements of Competence for Using Teach-back Effectively," which of the following is one of the teach-back suggestions?

A. Use a caring tone of voice and attitude
B. Use non-shaming, open-ended questions
C. Use reader-friendly print materials to support learning
D. All of the above

3. Which of the following is not on the list of criteria for IRB approval of research, under Title 45, part 46.111 of HHS' Protection of Human Subjects?

A. Minimize risks to subjects by using sound research design that does not unnecessarily expose subjects to risk
B. Evaluate risks and benefits to see that risks to subjects are reasonable in relation to anticipated benefits
C. Provide subjects with adequate compensation for their time and risk in participation
D. Monitor the data collected, as appropriate, to ensure subjects' safety

4. Which of the following is not a capability of electronic data mining tools, according to Judith Birk?

A. Look at metrics of studies reviewed by the full board or at an expedited review
B. Drill down to department level to see which institutional areas require more resources
C. Automatically compare an IRB's full board discussion of a study with another institution's full board discussion of the same study
D. Measure turnaround time at each step of the protocol submission process with real-time reporting and data visualization capability