IRB ADVISOR

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INSIDE

RELIAS MEDIA

Single IRB Common Rule Changes Arrive in January

By Melinda Young

Academic institutions are grappling with ensuring their IRBs are prepared for the January 2020 deadline to move multisite research to a single IRB. This deadline looms over all policy and procedural changes.

"There are plenty of institutions out there that are not ready for this change," says **Ann Johnson**, PhD, MPH, CIP, IRB director and adjunct professor at the University of Utah

The evolution to a single IRB will be tough on human research protection programs (HRPPs) and IRBs for a while, predicts **Julie Ozier**, MHL, CHRC, CIP, director of the HRPP at Vanderbilt University and Medical Center.

"I think it's going to be a mass of confusion for a while, until it gets settled down," Ozier says. "Last year, you were allowed to transition studies that met certain criteria to the new Common Rule. But in January, when a single IRB review requirement goes into effect, all those studies will have to comply."

> "THERE ARE A LOT OF PEOPLE WHO GOT CAUGHT IN WANTING TO TRANSITION STUDIES TO THE NEW COMMON RULE BECAUSE IT RESULTS IN FEWER REVIEWS FOR INVESTIGATORS."

Until 2020, the transition will involve exempt or expedited studies. Starting on Jan. 20, 2020, those studies will need to use a single IRB. IRBs might not be prepared for the January deadline, Ozier says.

"There are a lot of people who got caught in wanting to transition studies to the new Common Rule because it results in fewer reviews for investigators," she says. "But now they're at that point and have to go backward and convert that to a single IRB."

Even if researchers are not enrolling participants in a study, they will have

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to transfer the study to a single IRB, Ozier says. "It's a narrow niche that will trip up a lot of people," she adds.

Several groups representing research institutions wrote to the Office for Human Research Protections (OHRP), expressing concern that OHRP's deadline for cooperative research and use of a single IRB will apply to studies that began before that date.

"In the absence of prompt and clear guidance, institutions will be forced to begin complying with an interpretation that runs counter to the best interests of the federal government and the U.S. research enterprise or will be out of compliance beginning Jan. 20, 2020," reads the May 1, 2019, letter written by the Association of American Medical Colleges, the Association of American Universities, and the Association of Public and Land-grant Universities to OHRP's Jerry Menikoff, MD, JD. *(The letter is available online at: http://bit.ly/2osViRp.)*

Over the years, the University of Utah has focused on single IRB processing, Johnson says. "We're ready and have been ready for a while, so we're not afraid of this transition," Johnson adds. "We have the infrastructure and skills, and we know how to do this."

The single IRB and Common Rule changes also affect how IRBs handle informed consent. "One of the things we did because of the revised Common Rule and single IRB is we got rid of our consent template, which is a very bold thing to do," Johnson says. "We don't need a consent template to be a compliant IRB. The reason we got rid of our consent template is because we wanted to get rid of this notion that a consent form is supposed to look a certain way. It's not."

The idea is to re-engineer notions and ideas about informed consent so that study personnel do not believe consent forms should look one precise way, Johnson explains.

"As long as the informed consent document says the things the Common Rule says it needs to say, then you have a consent form and it works," she says.

Under the Common Rule changes, IRBs should make decisions about informed consent up front, Ozier suggests. "Decide how it's going to be handled and be flexible because it could change over time," Ozier says. "You have to decide who is going to do what and when, on a study-by-study basis, which is different from what institutions are used to."

In the new Common Rule era, it would be helpful for IRBs to let go of preference-based changes to the informed consent document, Johnson notes. Preference-based changes involve how an informed consent form looks or how certain sentences and paragraphs are structured, she explains.

"These preferences don't have any basis in criteria for approval or federal regulations, or are related to institutional policies," Johnson says. "These preferences are just how the IRB likes it."

It is more efficient to let go of those personal preferences and focus on what is important. "At Utah, we help our staff, research personnel, and other reviewing IRBs understand there is a difference between policy vs. preference on what the informed consent says," Johnson says. "It's easier for my staff to review an informed consent if it looks like the ones they're used to, but that doesn't mean it shouldn't be approved by the IRB."

Instead, IRBs can give investigators research language that is specific to policies and teach IRB members and HRPP staff how to understand the difference between quality and preferences, she adds.

For IRBs that are not ready for the single IRB world, there are modifications they might need to make, Johnson says. "We needed to modify our electronic system for submissions, and we had to retrain all of our staff and investigators," she explains. "It took a lot of time. It's a daunting task."

Keep in mind that no one is expected to make this transition perfectly on day one, Johnson notes. "We're all in a learning process of what best practices for a single IRB are, and it's OK if we're still learning and making things better after that effective date," she says. "I'm hopeful that people will take courage that we're all in this together, even after the effective date, and we'll still work on this and make it a good process."

The takeaway message is to be prepared as well as possible, but to accept the need to keep learning more about the transition after the effective date, Johnson adds. ■

Focus on the Differences Between IRBs and HRPPs

Use SMART IRB agreement

By Melinda Young

As research institutions move toward a single IRB model and more studies are deemed exempt, there is a greater need for all stakeholders to understand the differences between an IRB and a human research protection program (HRPP).

"Many people think about the IRB as the HRPP, and that has never been true," says **Ann Johnson**, PhD, MPH, CIP, IRB director and adjunct professor at the University of Utah. "The IRB is a large component of human research protection programs, and everyone knows what an IRB is, so there's a case of mistaken identity. With the new changes of the Common Rule and a single IRB coming through, you should make sure you know the two are separate. They work together, but are separate."

HRPPs still are necessary under the new Common Rule. Some functions will be shifted to the single IRB, but many activities will need to stay with the HRPP, says **Julie Ozier**, MHL, CHRC, CIP, director of the HRPP at Vanderbilt University and Medical Center. "How do we structure the HRPP so we don't miss anything?" Ozier asks.

One method is to start with a SMART IRB agreement. This helps IRBs decide which will handle the privacy review and study investigator qualifications, Ozier suggests.

SMART (Streamlined, Multisite, Accelerated Resources for Trials IRB Reliance platform) helps streamline the IRB review process for multisite studies. It was launched in 2016 and is funded by the National Institutes of Health (NIH) Clinical and Translational Science Awards (CTSA) program. SMART IRB information and tools, including a SMART IRB agreement, are available at no charge at: https://smartirb.org.

"There are a lot of pieces that HRPPs take on that are outside the IRB, such as ancillary committees, oversight of what's being billed for research, and how it fits with Medicare, auditing, and compliance," Ozier explains.

Research institutions should be flexible in deciding which group will be responsible for monitoring and which is responsible for auditing if something does not look right, Ozier says. "Those things have to be hammered out," she adds.

Ozier and Johnson offer these suggestions for delineating the activities of the IRB from those of the HRPP:

• **Educate researchers on the difference between IRBs and HRPPs.** "It's really important to educate our investigators to understand the difference between the IRB and HRPP," Johnson says. "Tell investigators what they have to do at the institution, even if they are using a single IRB for the review."

One helpful educational tool is a work chart for the HRPP. "The HRPP work chart can list out all of its components and show that the IRB is just one component," Johnson explains. "HRPP has leadership and a reporting structure, and this chart helps researchers understand that it's different from the IRB, although we work together."

Education includes teaching investigators about federal regulations and the IRB review process. "We essentially help them understand how those regulations list out criteria for IRB approval," Johnson says. "HRPP components that are not on that list are things the HRPP will help them with."

• Describe who is responsible for which duties. "Decide who is responsible for monitoring, who is responsible for auditing, and if something doesn't look right, who is responsible for reporting that to the federal government," Ozier says.

Institutions can use a written policy and procedural document to determine which role each party is fulfilling, Johnson says. "We want to ensure our institutional policies and state laws are met," she says. "Every state is different, and those differences could affect a lot of different parts of a study."

For example, state laws could affect consent language related to studies that use fetal tissue, or whether certain participants could be recruited for research, she adds.

Institutions often use separate reviews for conflicts of interest, radiation safety, and institutional biosafety. These boards and reviews are part of the process, and the local HRPP could be the one communicating those review results to the single IRB.

"If our local IRB staff communicate with the single IRB staff, it goes better," Johnson says. "We know the same words, jargon, and we have the same purpose, so it's better if my staff communicate directly with the IRB reviewer, rather than have each committee speak with them."

• Review studies to see which could be reviewed by the central IRB. "See the type of studies that happen at your institution and which ones have the potential to be required for a single IRB," Ozier says. "You don't have to outsource, if it's not required, but a lot of institutions choose to outsource the commercial, industry studies."

Make these assessments up front:

- Should the IRB outsource federally funded research that requires a single IRB?
- Should the IRB outsource industry-sponsored research?
- What process does the HRPP use to handle outsourced research?
- What processes are established to determine exempt research?

IRBs need a process for making exempt determinations, Ozier says. "Those are studies that don't rise to the level of being required for review by a single IRB," she explains. "While there are some commercial IRBs that will make exempt determinations, that's not really common."

As the Common Rule was discussed, there was a debate over who would have the authority to determine whether a study is exempt, Ozier notes. The final Common Rule stated that the IRB does not have to be the sole organization making that determination. But this does not mean that IRBs and HRPPs need to leave this determination to investigators, she says.

"Most of the time, the study is not exempt," Ozier says. "It's hard for investigators to make that determination on their own because they're too close to the project."

HRPPs probably should keep the privacy board in-house because the external IRB wouldn't have access to some important information, such as medical records within the covered entity, Ozier says.

• Decide on activities that will stay with the HRPP. "If you decide to outsource some things that are done by a single IRB, then the next step is to determine which things you want to keep in your HRPP," Ozier says. "For example, do you want to maintain oversight of the privacy board? Do you want to maintain oversight of verifying qualifications of investigators and study personnel? Those are the kinds of things that help a HRPP decide how involved, or not, they want to be. It gives them some tools for things they will be able to monitor if they need to."

Local HRPPs are better poised to evaluate researchers' qualifications than are single IRBs, Johnson says. "Local institutions know their investigators and have a documented history of training and qualifications," Johnson says. "We verify everyone who has received training and has a curriculum vitae on file."

The local HRPP also is in a better position to evaluate whether investigators at their institution have the resources to conduct the study. "This would be hard for a single IRB to know," Johnson adds.

• Determine how the single IRB process will work. Here are some questions IRBs and HRPPs can ask as they figure out the new process:

- What will the process look like?
- Will the organization require every investigator to submit through the IRB office so the office can maintain a record?
- What activities will you retain locally?
- Will the organization make assessments?

"If you don't have that process in place and don't look at these studies, then the other IRB might not know the nuances specific to your institution," Ozier says. "They will need to know these

local considerations to make an assessment."

Local consideration worksheets can help with this process, she notes. "Investigators can fill these out with their HRPP, covering everything they can provide to the reviewing IRB," Ozier says. "We have worksheets we've done, and they are electronic surveys with a piece the investigator has to fill out and a piece for the IRB to fill out." ■

OHRP Holds Workshop on 'Pervasive' Data

Questions both ethical and technical on a tsunami of data

By Gary Evans

The unprecedented level of digital data available across an expanding electronic landscape poses complex challenges for IRBs as they attempt to provide ethical insight and ensure participant privacy.

The Office for Human Research Protections (OHRP) recently held a workshop on this issue, entitled "Privacy and Health Research in a Data-Driven World."

"We are currently living in a world in which previously unimaginable amounts of data are being generated and used for research purposes," said **Jerry Menikoff**, MD, JD, director of OHRP. "There is a tremendous potential to use these vast collections of data to learn more about health behavior of the population to the benefit of all of us as individuals."

Some of these data are collected in clinical care, but the public also is generating data through health monitoring devices, GPS location systems, social media, and information collected and shared on mobile apps.

"Health-related big data research promises new insights into treatments for a variety of conditions and diseases, in addition to innovative ways to support and maintain good health," he said. "However, currently, there is no consensus about appropriate ways to collect, store, and share these types of data. What are the appropriate trade-offs?"

To dig into this question, **Michael Zimmer**, PhD, associate professor in the department of computer science at Marquette University, presented research on what he called "pervasive data." For the purposes of his ongoing research, Zimmer defined pervasive data as "rich, personal information generated through digital interaction and available for computational analysis."

In general, Zimmer said, pervasive data research:

- gathers digital data about people;
- uses computational methods to assess an individuals' or groups' health, habits, routines, or beliefs;
- may be collected frequently without the studied populations' knowledge.

IRB Challenge

Challenges for IRBs in dealing with pervasive data in research include the concerns with privacy, informed consent, and harm to human subjects.

"A lot of what we are seeing happening today in this space of big-data ethics and research is creating confusion," Zimmer said. "[There are] some gaps and shifts in understanding of fundamental core principles around research ethics."

Other issues for IRBs include the increasing ease of performing big data research, and the fact that some researchers in this emerging area may lack traditional ethics training, he said.

"We are seeing a lot of scientists and researchers in research communities who don't have a tradition of dealing with human subjects as defined by the regulations," he said. "I'm working now with computer scientists and data scientists who don't have a long history of dealing with IRBs, or understanding there is actually a human being attached to this piece of data they are analyzing."

While that insight suggests caution, pervasive data often are easy to access and disseminate. "If I ask one of my undergrads to give me 5 million tweets about something, they can have them for me before I get home tonight,' Zimmer said. "It's a very different kind of research environment than 20 years ago."

To explore these questions, Zimmer and colleagues have formed a research website called "Pervade: Pervasive data ethics for computational research," available at: http://pervade.umd.edu/. "We are trying to understand what IRBs think about pervasive data, and how they actually review these protocols," he said. "Are they adequately prepared to manage these kinds of research projects?"

Researchers of a 2017 study of

59 IRBs in the U.S. found that 93% of respondents reported that "online data" raise research ethics issues. However, only 55% said they believed their IRBs were well versed in the technical aspects of online data collection, Zimmer said. Only 57% believed their IRB had the expertise to stay abreast of changes in online technology, he added.[1]

IRB Survey

Earlier this year, Zimmer and colleagues recruited IRB members via email and social media to assess knowledge and attitudes on pervasive research. They received 79 valid responses, 80% of which were from a college or university. About half of IRBs responding said they understand the ethical dimensions of pervasive data research.

"We are still in the process right now of going through these results, but we're already finding interesting things," he said.

For example, approximately one-third of IRBs reported they were reviewing a study involving pervasive data about once a week. "They had 50 or more protocols they were seeing come through [annually]," he said.

Only 25% of respondents said that their IRB had sufficient technical understanding of what it means to engage in pervasive data and use these kinds of protocols, he said.

"When you start introducing pervasive data and these new protocols and data sources, that technical understanding drops," Zimmer said. "There is a gap there for us to fill to make sure IRBs understand what these protocols mean."

Most IRBs responding were not conducting any specific training on pervasive data, with only 30% indicating there is education on this for IRB members.

Zimmer and colleagues presented the IRBs with hypothetical research proposals using pervasive data with different variables. The proposals varied by level of consent, whether the data was considered public (like a Twitter feed), or not public (like a health forum that requires a login), he explained. Other variables included anonymity of participants and whether the researcher was adhering to the terms of service on the platform they used.

"WHEN YOU START INTRODUCING PERVASIVE DATA AND THESE NEW PROTOCOLS AND DATA SOURCES, THAT TECHNICAL UNDERSTANDING DROPS."

IRB members were asked to classify the hypothetical proposals into four categories: non-human subjects research, exempt, expedited, and full review. "In most cases, focus on the publicness of the data was a key indicator," he said. "If the data were [already] published, they were generally putting that in as non-human subjects research or exempt status."

Research Scenarios

For example, a researcher is studying a Twitter archive that somebody collected and sharing that with another researcher to understand tweets about a political event, he said.

"They are not getting consent because the data was collected by someone else and the data being used is public," he said. "It is anonymous because they took measures to de-identify. Perhaps not surprisingly, most responses said this is either not human subjects research, or was exempt."

In another scenario, a researcher wants to look at mental health records of university students and their social media presence. The researchers plan to collect informed consent and identifiable information from participants.

"The data are quasi-public. Maybe social media stuff is public, and we won't anonymize because the point is to understand students and perhaps have an intervention," he said. "All of the respondents said this will be expedited or to full review."

Other hypothetical pervasive data protocols fell somewhere between these two examples, with some IRBs recommending more oversight and review and others willing to exempt them. "This often came down to this question of sensitivity in terms of what the researcher was doing," he said.

For example, a research scenario examined public Twitter feeds to predict risky drug use behavior. "We are not going to get consent, but it is public," he said. "We are going to de-identify, and we are following the terms of service, but we now have a bigger spread on how people responded to this."

Overall, 38% of IRB respondents listed this as non-human research, and 33% said it should be exempt. However, 21% said the protocol should be expedited, and 7% said it should undergo full review.

There are not necessarily right or wrong answers, as Zimmer used the hypothetical protocols to show where there is broad agreement as well as results that diverged across the board.

In another example, a researcher trying to predict election outcomes proposes to aggregate and analyze comments on a newspaper website, a practice that is forbidden by the publication's terms of service. The IRB results were polarized, with 28% saying it was not human research and 33% saying it should be subjected to full IRB review. The latter result was driven by the proposed violation of the newspaper's terms of service, Zimmer said.

"There is a lot of variance showing up on some of these complex, interesting, but not outrageously unlikely, research scenarios that use pervasive data," he said.

Zimmer and colleagues will continue researching pervasive data and meet with stakeholders to develop recommendations. "We have to start thinking about coming up with some of the key principles," he said. "We are hoping to bring in data from multiple viewpoints — not just IRBs, but actual users whose data are being collected. We are talking to researchers and the companies that run these platforms. Hopefully, we will come up with a toolkit with a set of guidelines to help make this less confusing." ■

REFERENCE

1. Vitak J, Proferes N, Shilton K, et al. Ethics regulation in social computing research: Examining the role of institutional review boards. *J Empir Res Hum Res Ethics* 2017;12:372-382.

Is 'Informed Consent' an Oxymoron?

Study finds low comprehension with concise forms

By Gary Evans

A study asking readers to consent to a short form containing only the key information about the research resulted in suboptimal comprehension, suggesting participants only skimmed through it or skipped it outright.[1]

The lead author of the social science study is **Evan Perrault**, PhD, assistant professor of health communication at Purdue University. Perrault and co-authors recently published the findings in light of revisions to the Common Rule that call for "concise" consent documents that "facilitate comprehension." The changes were enacted in part because informed consent documents have trended to lengthier forms that may leave participants consenting to something they do not completely understand.

The researchers developed a 71-word consent process for an online study, then tested participants' comprehension of the information. Participants could either read the concise summary and proceed directly to the study, or get more information on the research to which they were consenting. All 429 participants bypassed this option and proceeded to the study, which was about preventing sexually transmitted diseases. The concise form included all the standard research parameters, but when questioned about their consent, "about one-third of participants did not know how long the study would take, 77% did not know who the primary investigator was, and 14% did not know that their responses would be anonymous," according to researchers.

Participants indicated they liked the brief consent process, but many clearly did not comprehend the limited information or simply skipped over it. "If we want to continue referring to informed consent as informed, future research should be welcomed and supported by IRBs to seek ways to apply the newest Common Rule guidelines while increasing comprehension; otherwise, informed consent will likely always remain an oxymoron," the authors concluded.

IRB Advisor asked Perrault to comment on the research in the following interview, which has been edited for length and clarity.

IRB Advisor: What are the implications of your study for IRBs, particularly as they try to address the call for more "concise" informed consent forms in the revised Common Rule?

Perrault: The study dealt only with an online study, so its conclusions cannot be generalized to all forms of research that IRBs oversee. However, at least for online, minimal-risk online studies, this study helps to showcase that still more work is needed to find ways to put the "informed" into "informed consent." I would encourage local IRB managers across the U.S. to work with colleagues in the social

sciences at their institutions to develop and test novel ways to ensure better information comprehension in their consent processes.

IRB Advisor: Does your study and the prior research you cite indicate that many research participants today do not really comprehend the research to which they have consented?

Perrault: I think the bigger question here relates to participants fully reading the forms. As researchers, we can't expect participants to comprehend information if they're not actually reading the forms. While our study did not assess whether participants read the concise consent form, a prior study of mine that also tested shorter forms (about 150-190 words) found that about 21% did not read the form at all, and about 69% skimmed the form. Future research should continue to focus on ways to encourage participants to fully read the content these forms contain. Only then can we expect comprehension to increase.

IRB Advisor: Can you elaborate on the finding that participants only comprehended about half the information in the short consent form?

Perrault: The short consent form provided to participants included many of the elements the revised Common Rule indicates are important to include in any consent form (the purpose of the study, the study duration, potential risks, contact information).

Questions to assess recall of these pieces of information were asked, with results revealing that greater than half of participants were unable to remember the primary investigator of the study (77%), the risks they many encounter in completing the study (83%), and the contact information of the university's IRB (98%).

IRB Advisor: You make an interesting point about the impact of social media on the willingness of people to read a long consent form. Given that participants cannot, for ethical reasons, be forced to read a form, do you think this idea of informed choice may emerge as an alternative to informed consent?

Perrault: It is possible. As I stated in the paper, participants in the current study had the opportunity to learn more about the study beyond the 71-word form they received if they wanted to. No participants did. About 15% of participants indicated via an open-ended response that they appreciated that they were offered this choice as part of the informed consent process. ■

REFERENCES

1. Perrault EK, McCullock SP. Concise consent forms appreciated — still not comprehended: Applying revised Common Rule guidelines in online studies. *J Empir Res Hum Res Ethics* 2019;14:299-306.
2. Perrault EK, Keating DM. Seeking ways to inform the uninformed: Improving the informed consent process in online social science research. *J Empir Res Hum Res Ethics* 2017;13:50-60.

Protecting Research Data in the Digital Age

Use vigilance and common sense

By Gary Evans

With big data comes great responsibility. The increasing array of devices and systems to access, store, and transfer research data calls for diligence and common sense to prevent breaches.

How seriously is the research community taking this threat? The National Institutes of Health has essentially hired hackers to constantly probe and test its database for the All of Us genome research project.

Adarsh K. Gupta, DO, MS, FACOFP, chair of the IRB at Rowan-SOM in Glassboro, NJ, addressed data threats at a recent Office for Human Research Protections workshop on privacy and health research.

"As ethics committee members, when you review research protocols be cognizant about the type of data storage option used by the researcher," Gupta said. "Are they using a cloud, USB device, or mobile devices? What security risks come with these?"

The short answer appeared to be "many," as Gupta reviewed the vulnerabilities of electronic devices and platforms. Using mobile devices poses a security risk unless steps to safeguard data are taken, he emphasized. If possible, IRBs should offer an option for researchers to lock down data, such as on a secure cloud storage or encrypted mobile and portable devices. Another common-sense point is to limit storing sensitive information as much as possible.

"If you don't put it out there, it is safe," he said. "If you do, you are liable and you have to keep an eye on that."

Secure data are essential to comply with federal and state laws, protect the identity of participants, and preserve the integrity of the research. "Integrity means the data have not been altered or changed through some breach," he said. "Lastly, make sure you have a secure copy in case of loss or theft of data."

There are many regulations concerning data security, but HIPAA overrides all others, he said. If confidentiality is breached, the ramifications include potential embarrassment to participants and the risk of misuse of their personal information. "Those are the things we worry about," Gupta said.

Some investigators equate conducting research on their phones to electronic banking. While financial institutions typically will protect customers from fraud and restore funds, investigators have no backup unless they have made a secure copy of their data, he emphasized.

"That's why it's important for researchers [and IRBs] to be proactive and make sure these kinds of breaches don't happen," Gupta said.

It is not uncommon for researchers to underestimate the risk to mobile phone cloud data. "Don't put any protected health information on the cloud environment unless it's really needed," he said. "That's the first thing — minimize putting any identifiers anywhere. If something is put on the net, it's there somewhere in one form or other and somebody may find it and access it."

Mobile devices have advanced so much a phone may have more computer functions than a desktop. "You can do work with Excel, PowerPoint, add a picture — everything is on there," he said. "It is very useful, no doubt, but we have to worry about what is on the phone and how you are using it."

For example, your phone could be at risk in a Wi-Fi hotspot if a hacker uses a Trojan virus to capture data. Some downloadable apps contain malware that can attack your phone data, he adds.

"Many health researchers may not know much about technology," he said. "I have seen researchers who have no password on their phone. That's the biggest security risk for a phone."

For this and other reasons, it is a good practice to use separate phones for work and private calls. The work phone can include encryption software to log and access files that are not stored on the mobile device. "Be aware which cloud you are using," Gupta said. "At our institution, we have a secure cloud we provide for all researchers, and they are only allowed to use that."

Mobile phone security often is improved through software updates. Gupta recommended not deferring these when prompted to by a legitimate source.

Portable USB drives also call for common-sense measures, including not taking one of unknown origin and plugging it into your computer. "Make sure you keep the data encrypted on these devices," he added.

Do not assume, as many do, that email is a secure form of data transmission. "Email opens up to the whole world," he said. "A lot of this comes down to what data is being collected."

In cases of research for publication, he said, data can be anonymized by removing all 18 of these HIPAA personal health identifiers:

- Names;
- Exact location;
- Exact dates (except year);
- Phone and fax numbers;
- Email addresses;
- Social Security numbers;
- Medical record numbers;
- Insurance plan number;
- Account numbers;
- License numbers;
- Vehicle information;
- Device information
- IP numbers;
- Biometric information;
- Full face photos. ■

Methods to Improve the IRB/PI Relationship

Everything is situational

By Melinda Young

There are natural conflicts between IRBs and principal investigators, but IRBs can take several steps to improve this crucial relationship.

For instance, IRBs should treat everything on a case-by-case basis, depending on the situation, the principal investigator (PI), and the IRB's policies, says **RoseAnn Fleming**, CIP, interim director of the University of Southern California IRB.

If there is a policy disagreement or issue with an investigator, then the IRB director can quote the policy. IRBs that use internal standard operating procedures (SOPs) also can cite those in explaining decisions to PIs.

"Is the PI's expectation reasonable? If not, then why?" Fleming says. "If it is reasonable, why hasn't it been met?"

Fleming suggests IRBs use these methods to improve the IRB's relationship with PIs:

• Keep communication door open. "Talk to staff and find out what their everyday work is like and what are the most common reasons for sending PIs back-up questions," Fleming suggests.

When PIs contact Fleming, it usually is a sign that they are frustrated, upset, and did not get what they wanted, she says. "My goal is to see what's reasonable. I try to accommodate them, but I also put the responsibility back on them."

When a study goes through the IRB process several times, it is likely because there is miscommunication somewhere, Fleming says. "It's my goal to find out where that miscommunication is," she explains. "Oftentimes, it's because PIs are told to do something they don't want to do, and I have to tell them why they need to do it."

The problem often can be resolved when IRB staff tell PIs why they made that decision. They can connect it to policies and regulations and explain how their job is to help facilitate the research process while protecting human subjects, Fleming says.

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"When they understand why you're doing it, they are more reasonable," she adds.

• Use humor to break the ice. "Each analyst has their own way of dealing with different investigators, and I personally use humor because that breaks down the angry PI," Fleming says.

Humor puts people at ease. "I usually tell an investigator that I'm not a scientist and I don't play one on TV," she says. "My other line I use is: 'The answers I have to your questions are like adult diapers, everything depends on something else.'"

After that icebreaker, Fleming will launch into how a study can go from exemption to full board, based on details about drug use and whether identifiers are used. "The type of review you're doing depends on what you're doing in the study," she adds.

• Invite PIs to be part of the process. Sometimes, Fleming invites investigators to become IRB members. Her theory is that if a principal investigator is concerned about how the IRB works, then the PI could join the board and help change procedures, she says.

"Most say, 'No, thank you,' but once in a while they'll say, 'Yes,'" Fleming says.

Once PIs begin to understand how the IRB office and process works, they can become advocates for this check and balance in human subjects research. "They might go out and tell their peers, 'I hated the IRB at one point, but I understand them now,'" she says.

The investigators who accepted Fleming's offer have become the best advocates for the IRB, she notes. "Their expectations for other researchers were higher than their expectations of themselves, at the beginning," she adds.

Fleming's approach is based partly on her experience of working in clinical trials. "I know what their frustrations are," she says. "I once hated the IRB, too, but I know there are legitimate reasons why they're asking these questions."

• Instill policy of zero tolerance

for bullying. "I will not tolerate abusive PIs to staff," Fleming says. "Our institution has a policy, and I refer them to that policy."

Fleming has met with PIs to let them know their behavior was unacceptable. Her conversation with them is along the lines of "We are all here to do our best and accommodate you, but you have to understand you can't go around screaming at people," she says.

If it were necessary, she would escalate the issue to human relations, but that rarely is the case, she adds.

• **Create policies to ensure a fair turnaround timeline.** "We have a queue that new applications go into," Fleming says. "They're pulled out in the order they're received."

If the IRB asks nonscientific questions, then that review will return to the PI to resolve the issues. In a few cases, PIs prefer their protocols are first reviewed by a member of the board rather than IRB staff. Those studies are sent to the vice chair, Fleming notes. "If questions come from a peer, they're more accepting of it," she says. But those studies might take longer to review because they do not go through the usual process.

Developing ways to form an amicable working relationship with PIs is a good way to improve human research protection goals. For instance, IRB members and staff who PIs trust can be advisors. With their guidance, studies will go through the review process more efficiently and quickly.

There are good submissions and some bad submissions among the 2,000 new applications the IRB sees each year, Fleming notes. "Our volume increases every year," she says. "Our goal is to help those who submit not-so-good submissions improve their applications." ■

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CME/CE QUESTIONS

1. **Under the new Common Rule, which major change will occur on Jan. 20, 2020?**

   a. IRBs will have to change exempt determinations.
   b. A single IRB review requirement goes into effect.
   c. All formerly expedited reviews now will be exempt.
   d. Biospecimen research will no longer require an IRB review.

2. **How might IRBs improve their relationships with investigators, according to RoseAnn Fleming, CIP?**

   a. Give investigators a written list of acceptable and unacceptable questions to ask IRB staff.
   b. Have research staff sign off on the four-way ethical test, including: Is it the truth? Is it fair to all concerned? Will it build goodwill and better friendships? Will it be beneficial to all concerned?
   c. Use humor as an icebreaker when speaking with investigators.
   d. Ask IRB staff to accede to investigators' wishes when it does not conflict with policies and regulations.

3. **Michael Zimmer, PhD, listed challenges for IRBs in dealing with pervasive data in research that included the expected issues of anonymity and informed consent. Which was cited as another concerning issue in this type of research?**

   a. Research data is easily hacked and falsified.
   b. Researchers may lack traditional ethics training.
   c. Blurred line between social and medical research.
   d. Selection bias often undermines conclusions.

4. **Adarsh K. Gupta, DO, MS, FACOFP, said researchers at his institution are only allowed to store data on:**

   a. the facility's secured cloud.
   b. encrypted mobile devices.
   c. a USB device with remote erase.
   d. military-grade servers.

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