IRB ADVISOR

YOUR PRACTICAL GUIDE TO INSTITUTIONAL REVIEW BOARD MANAGEMENT

INSIDE

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Deadline Extended for Common Rule Compliance

'There has been absolutely no guidance out of OHRP'

By Gary Evans, Medical Writer

With finalization of the revised Common Rule postponed for at least six months — and possibly one year — IRBs should continue preparing to comply with the regulation as they await additional clarification and guidance, advises **David Borasky**, MPH, CIP, vice president of compliance at the WIRB-Copernicus Group in Durham, NC.

Most of the requirements of the final rule published last year were to become effective Jan. 19, 2018. However, the Department of Health and Human Services (HHS) and a host of other federal agencies recently issued a stopgap "interim final rule" that moved the effective date to July 19, 2018. That six-month delay is likely to extend to a full year because the federal agencies "are developing a notice of proposed rulemaking in order to fully engage regulated entities and the public … until Jan. 21, 2019," the federal notice states.[1]

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"They go on to say the additional time provided will allow sufficient time for the notice and comment rulemaking process to be completed," Borasky says. "It sounds like their intent is to have a one-year delay."

The situation may become clearer

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after an expected update and discussion at the March 13-14 meeting of the Secretary's Advisory Committee on Human Research Protections (SACHRP), he says. Borasky is co-chair of SACHRP's Subpart A Subcommittee, which advises the HHS Office for Human Research Protections (OHRP).

"My hope is that, going forward, there is a bit more transparency around the rulemaking process and we aren't sort of hanging on until the final hours to find out if something is going to go forward or not," Borasky says. "But clearly, they are telegraphing the idea that they are really thinking of a one-year delay, not a six-month delay."

IRB Advisor asked Borasky some additional questions about this development in the following interview, which has been edited for length and clarity.

IRB Advisor: Can you comment on why you think it was necessary to delay the rule?

Borasky: In depends on your perspective. We [at WIRB-Copernicus] were prepared to implement the rule as written on the implementation date. It terms of why [the delay] was necessary, I look at the Good Cause section on that interim final rule. It is noted that representatives of the regulated community and HHS's own advisory committee — SACHRP — have requested a delay in implementation of the 2018 requirements. They cite the final rule's complexity and the lack of guidance and the need to revamp processes, procedures, and systems. To some extent, that is true.

There has been absolutely no guidance out of OHRP. I think SACHRP, in part, recommended the delay because there are a number of things in the new rule that would benefit from having guidance from the regulators in terms of what constitutes compliance. That simply is not in place yet.

IRB Advisor: You note that SACHRP has provided comments to OHRP on a few different aspects of the rule.

Borasky: None of those recommendations have yet been issued as guidance, or even as draft guidance, out of OHRP. I think the regulators, to their credit, understand that there are some aspects of the rule that are certainly new, and perhaps a bit nuanced and complex, and that the regulated community would be well served to have some guidance on how to implement those. What is unfortunate is that they had a whole year to prepare that guidance or instruction and didn't take advantage of it. [They] waited until the 11th hour to issue that delay. That part of it is a bit disappointing. If they knew that the delay was going to be necessary for those reasons, it is a little frustrating that they waited so long to formally announce it.

IRB Advisor: In the interim, what do you recommend IRBs focus on in terms of compliance and preparedness?

Borasky: Hopefully, most IRBs have initiated some level of preparations because we found out so late that there would be a delay. It would have been a gamble that ultimately paid off — but a gamble nonetheless — to have not started any level of preparation to the new rule prior to its delay being announced. Assuming that most IRBs have started to take some level of action in terms of preparing for the final rule, presumably what is lacking is to complete those preparations.

Obviously, the one thing that could impact how IRBs implement the rule would be having OHRP or

other Common Rule agencies provide guidance on what compliance means for this rule. SACHRP has made recommendations in the areas of broad consent, behavioral interventions, and the transition provisions for moving on to the new rule. But those only exist as SACHRP recommendations. OHRP has not pointed at those and said, "That's exactly what we are thinking." I know some members of the IRB community look at SACHRP as a resource, but it's impossible to say to what extent their recommendations will be adopted by OHRP.

In the absence of any guidance, I think IRBs should stay on the course of preparing. There certainly are aspects of the rule that are not all that hard to decipher; for example, implementing a change in continuing review requirements for expedited research. You don't need a whole lot of guidance to explain what that means. The required elements of informed consent, with the exception of the key information provision, are relatively straightforward. So, I think [IRBs should continue] preparing their systems and consent templates or other tools that they have. Stay on that path.

IRB Advisor: Given the current antiregulatory political climate, there has been some suggestion that the Common Rule may not be finalized for an indefinite period, going beyond this extension.

Borasky: I have heard some of those same concerns, and certainly the regulators did themselves no favors by not publishing the final rule until the last day of the previous administration. It seems that a number of people believe that this delay was announced so close to the implementation date due to the transition to the new administration. But nobody has said that definitively — that's just speculation. From the aspect of the administration having concerns about it, my opinion is that the new rule reduces regulatory burden. That certainly seems to be in the spirit of the current administration's approach. It had the endorsement of most of the Common Rule agencies. It is addressing issues that are important to the NIH, which has already announced similar policies like its single IRB, which are in harmony with the final rule. To me, that points to the rule being implemented at some point. ■

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Dissenting Opinion: New Common Rule Penalizes the Compliant

Single IRB 'a solution looking for a problem'

Many see the single IRB requirement in the revised Common Rule as a necessary sword to sever the Gordian knot of regulatory overlap and unnecessary delay of multisite review. **Suzanne M. Rivera**, PhD, is not one of them.

The single IRB requirement, to quote a phrase from Rivera's recent analysis of the situation, "is a solution looking for a problem."[1] Rivera is a bioethics professor and vice president for research at Case Western Reserve University in Cleveland.

"The existing regulations already permitted institutions to collaborate and defer to one another for IRB review," she tells *IRB Advisor*. "It wasn't necessary to change the regulations to require that because we already had the freedom under the old version of the Common Rule to do that."

For example, many academic medical centers rely on the National Cancer Institute central IRB for oncology research protocols. Similarly, many institutions collaborate with independent IRBs, Rivera says. Others have interreliability agreements with one another, which in Cleveland means research hospitals and universities can rely on each other's IRBs when needed to reduce redundancy and increase efficiency, Rivera says.

"The new version of the Common Rule that requires a single IRB for multisite studies, I feel, is going a step too far," she says. "It does not allow the discretion of the participating institutions to decide when a single IRB is appropriate and helpful versus when it is not. By requiring it in all cases for multisite studies, I fear there could be some unintended consequences."

These consequences, in Rivera's view, fall somewhat disproportionately on those already abiding to ethical imperatives, an argument somewhat similar to the old "forgotten man" theory in social science where the compliant pays for reforms necessary to rein in the violator.

For example, if a researcher commits some ethical breach, rather than single out the individual, the default position has been to penalize the larger group with new requirements.

"We should address bad actors by holding them accountable for violating the rules, rather than making the rules more rigorous across the board," she says. "I think the vast majority of researchers do follow the rules and uphold important ethical principles in the conduct of their research. But I worry when a few people, either by mistake or deliberately, violate the rules that there tends to be a reaction to make it harder to do research for everyone. I think that is counterproductive."

SACHRP previously recommended that the Common Rule outline penalties for rogue investigators and educate the public about the importance of human research.

"I thought those ideas were really important and valuable," Rivera says. "One of the ideas was an effort to educate the public, including patients and client populations, about the importance of the research. The other [recommendation] was penalties for investigators who, in an unauthorized fashion, try to reidentify specimens or data that had been deidentified. But neither of those suggestions made it into the proposed final rule." ■

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Give People What They Need in Informed Consent: Plain Language

Most research informed consent forms are written at a high school reading level when many people who are being recruited for studies might need language nearer to a fifth-grade level, according to a new study.

Researchers reviewed more than 200 informed consent forms, finding that the mean readability was at the 10th-grade level for the IRB-approved forms.[1]

For the study, researchers developed a plain language informed consent template that was at the fifth-grade level.[1]

"We aim for a fourth- to eighth-grade reading level for informed consent forms," says **Edith Paal**, MSJourn, MPH, IRB program manager at the University of Arkansas for Medical Sciences (UAMS) in Little Rock.

"That level is generally appropriate for our population," Paal says. "We need to make the information very clear to people in the consent process."

The need is there: "We were frequently getting requests to help simplify informed consent," says **Kristie Hadden**, PhD, associate professor in the college of medicine and executive director of the UAMS Center for Health Literacy.

The Center for Health Literacy worked with the UAMS IRB and the clinical translational research center to improve the institution's research informed consent.

"I researched best practices, problems, and did research with patients with low health literacy," Hadden says. "There is quite a lot of literature out there that demonstrates that informed consent for research is difficult for most people to understand."

While the average reading level in the United States is ninth grade, multiple studies have demonstrated that informed consent forms are written at a higher reading level, she adds.

"If you want people to understand the study, and if you want to provide informed consent from an ethical standpoint, then they need to be written at a sixth- to eighth-grade level," Hadden says. "When we established a baseline, looking back at informed consent from 2013 to 2015, we found the mean readability was 10th grade, so we knew we had room to improve."

People who have low health literacy and numeracy, meaning they struggle understanding numbers and quantitative information, have difficulty understanding a study's risks and benefits, she says.

"Risks are often expressed in percentages and proportions, and this can be difficult for a lot of people to understand," Hadden explains. "They might have a completely different view of the study than what the investigator intended."

The UAMS IRB works with investigators who initiate studies on improving their informed consent language.

"A lot of times, especially with investigator-initiated studies, we see the principal investigator, who is writing the consent form, is very well-versed in his or her subject, but is not cognizant that the consent's audience is not as familiar with the language," Paal says. "It's language that investigators use every day when talking with research staff and clinicians, but their words are not how their subjects would describe it."

For example, in the section on risks, the investigator might use the word "pruritus" to mean "itching," when "itching" would work just as well, Paal says.

Another common word informed consents use is "hypertension." This is a common word to investigators and healthcare professionals, but the average person might not know what it means, Hadden says.

"You can put 'hypertension' in a title and explain what it is at the beginning, but from then on use the words 'high blood pressure' because that's the language patients will use," Hadden suggests. "Write informed consent from the perspective of the participant."

Sponsored research also has informed consent problems, but it's easier for an IRB to encourage readability changes when it involves an investigator-initiated study.

"Industry-sponsored informed consents are the most challenging ones to read, but we don't have a lot of flexibility in what we can tell them to change," Paal says.

Or, even if an IRB has flexibility, there's the logistics problem, says **Jennifer Holland**, JD, IRB director at UAMS IRB.

"It would require a complete rewrite of the consent form," Holland says. "We can ask sponsors for certain terms to be put into lay language, but we just don't have the manpower to rewrite it, and they're usually not willing to make an extensive change."

Giving feedback to sponsors on their informed consent readability can lead to some positive changes. Some sponsors have said they would work on improving the language and did make changes that improved upon the original version, Holland notes.

> "IT'S LANGUAGE THAT INVESTIGATORS USE EVERY DAY WHEN TALKING WITH RESEARCH STAFF AND CLINICIANS, BUT THEIR WORDS ARE NOT HOW THEIR SUBJECTS WOULD DESCRIBE IT."

One possibility, which the IRB has not yet implemented, is to supplement the industry sponsor form with a brief summary with highlights tailored to the local audience. It would be something easy to read quickly and it would specifically refer to the main consent form. Or, it could be a brochure that uses pictures and simple language, Paal says.

The informed consent study found that about half of investigators voluntarily used the the plain language template, Hadden says.

"More importantly, there was a 658% increase in written informed consents that were written at eighth-grade level or below," she says. "If they didn't use the template to improve the reading level, it was too high — a 10th-grade level."

The next step in improving informed consent readability is to study the results of improvements.

UAMS has not yet tested the simplified template in a randomized trial, but when the institution conducts this study, the results could help the IRB decide on next steps.

"One of the things I found in designing our next step for the research agenda is that a lot of studies have looked at a simplified informed consent vs. a standard informed consent, and not many demonstrated a difference in comprehension," Hadden says.

"Participants may prefer the simplified version, but they rarely found meaningful differences in comprehension," she adds.

Hadden theorizes this is because participants were asked questions that were difficult to comprehend — even at a high reading level.

"When we do a study, we'll use the simplified template and include the teach-back method of confirming understanding," Hadden says. "We'll ask people to explain the study in their own words to the research coordinator."

This should help the study discern comprehension differences between the plain language informed consent and the standard consent. "We'll find out how the template works for participants of low health literacy," she adds. ■

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Tips for Simplifying Informed Consent Language

Use white space, simpler words, Q&A

Using plain language in informed consent forms means exchanging medical and statistical jargon for words that people with low health literacy and low health numeracy would understand.

It's not easy, but there are strategies that can help IRBs and investigators improve the readability of their informed consent documents.

The following are suggestions from IRB professionals:

• Develop a plain language template. IRBs can help investigators get a good start on improving readability through the development of a plain language template.

"It's different from typical templates out there," says **Kristie Hadden**, PhD, associate professor in the college of medicine and executive director of the University of Arkansas for Medical Sciences (UAMS) Center for Health Literacy in Little Rock.

"We wanted to develop a template that could be used by every investigator at UAMS," she says. "We used health literacy best practices, plain language best practices, and we made sure it complied with legal requirements and had all of the necessary elements."

The template also needs to be easy to use and benefit both researchers and research participants, she notes.

UAMS implemented the 10-page template after two years of development. They encourage investigators to use it and give them assistance to adapt their own informed consent information to the template.

"I look at the new submissions that come in, and I steer them to the template, saying, 'You might want to consider this, at least for future studies,'" says **Edith Paal**, MSJourn, MPH, IRB program manager at UAMS.

Sometimes, IRB staff will improve a study's informed consent form. Then they'll email it to the investigator, asking if the modifications will work, Paal says.

"We find when we do the legwork on these things, they are quite appreciative," she adds.

> "WE USED HEALTH LITERACY BEST PRACTICES, PLAIN LANGUAGE BEST PRACTICES, AND WE MADE SURE IT COMPLIED WITH LEGAL REQUIREMENTS AND HAD ALL OF THE NECESSARY ELEMENTS."

The template is available online at: http://bit.ly/2o4hYU9.

The template puts standard informed consent information in as simple of language as it can, including this sampling of sentences:

- "We are asking you to be in a research study."
- "You do not have to be in the study."
- "If you say yes, you can quit the study at any time."
- "Please take as much time as you need to make your choice."
- "You can still get your medical care from UAMS even if you are not in the study."
- "This form may have words you don't understand. Research staff will read it with you, if you like."
- "The local study team will know your name and have access to your information."
- "We will do our best to make sure no one outside the study knows you are part of the study."
- "There are people who make sure the study is run the right way. These people may see information from the study about you. They are (insert study sponsor or funding source; OHRP; UAMS Institutional Review Board, other institutional oversight offices, etc.)."
- "Being in the study may or may not help you, but may help people with (insert condition) in the future."
- "By signing the document I am saying: I understand that joining this study is voluntary; I agree to be in the study."
- "I know that I can stop any and all parts of the study at any time and nothing bad will happen to me."

• Involve IRB staff and research staff in process of improving informed consent. Research and IRB staff can help with developing the simple language template.

"We have an office that does development for some protocols and consent forms, so we were involved with researchers and exchanged several emails back and forth with their staff members," says **Jennifer Holland**, JD, IRB director at UAMS IRB.

IRB staff also met with researchers multiple times.

"It was a very long process, and we've changed and modified the template a few times," Holland says.

There were so many template drafts that Paal lost count: "I think there were 3 million drafts before we came up with the final one," she jokes. "There were lots of stakeholders weighing in."

Plus, the tweaking is ongoing.

"Every now and then, I'll notice this one word or sentence that needs tweaking, and we point that out and discuss it, and, if everyone agrees, we change it," Paal says.

In assessing the readability, IRBs could use Word's readability tool. It's not a perfect measure, but it gives a good idea of the document's reading level, Hadden says. IRB staff also can work with researchers on fixing wording problems they are unable to do on their own.

For example, Paal worked with a principal investigator who was a non-native English speaker.

"He had the consent form based on the template, and we went back and forth on its content," she says. "Finally, I told him that I have a few language fixes for him, and I'll fix it and send it back to him. He wrote back, 'You are reading my mind because I even showed it to my research assistants who are native English speakers, and we couldn't think of how else to word it.'"

• Remind research team that the template is designed to be modified. "One challenge we've faced is that principal investigators are not aware that the template is not set in stone," Paal says. "They can delete parts that don't apply to their studies."

At the beginning of the template's instructions, it specifically says to delete sections and language that doesn't apply, Holland says.

"As with any template, people sometimes skip past that, and a lot of times people use templates, but not in the best way for their study," Holland adds. "So even though we have the language in there, they may not delete anything and tend to skip down to the section they want to use right then."

Also, the study staff might write the consent form, basing it on the protocol that the investigator wrote. This means they use some of the same complicated language, not paying close attention to the need to communicate clearly and simply, Holland notes.

Then they'll plug it into the template, leaving the template language when they should have deleted some parts. They overlook things in the informed consent as they rush to complete the document so they can submit the protocol, she adds.

• Tweak wording of regulatory language. "One challenge we faced was that certain regulatory requirements have to be addressed, and the easiest way to address them is to use regulatory language," Paal says. "We did a lot of work on that aspect of making sure all regulatory requirements were met while using plain language precepts."

While going through this process of translating the regulatory requirements, Holland kept in mind the acronym SMOG, which stands for "simple measure of gobbledygook."

"It's a very fitting acronym for research consents and medical consents," Holland says.

• Keep in mind that there is no perfect solution. Moving to plain language in informed consent requires compromises.

Low Health Numeracy Also Is an Informed Consent Problem

Here's how to improve informed consent numeracy

Low health numeracy is a problem that could affect how well trials recruit and provide informed consent to potential participants. It's defined by how well people access, process, interpret, communicate, and act on numerical, biostatistical, and other numbers-related health information.

There are multiple ways IRBs and researchers can improve the way they present numbers and statistics in informed consent. The following are some suggestions and best practices developed by the Center for Health Literacy at the University of Arkansas for Medical Sciences in Little Rock:

• Simplify the numerical concept by presenting information simply enough that participants do not have to make their own calculations. For example, instead of recommending a 275-pound patient lose 5% of his or her body weight, suggest that he or she lose 14 pounds.

• Keep denominators the same for comparisons. For example, readers prefer proportions with larger denominators even when the fractions are equivalent, such as 5/10 instead of 3/6.

• Use visual aids when possible, including graphic displays and icons. For example, turn 25% into a picture of four icons representing people, and only one of the four is highlighted. ■

"In plain language writing, it's an exercise in compromise all the time," Hadden says. "You want to keep it as short as possible because people who are struggling with language don't want a 13-page document."

But if the form provides additional explanations, then that adds to its word count. The key is to eliminate what is unnecessary.

"There is a lot of unnecessary content in informed consent: A lot of paragraphs were copied and pasted from protocols, and there are methodologies that are not necessary for informed consent," Hadden says.

It's important to make the most important changes and to compromise on the ideal when perfection is elusive.

"It's not always possible to take out all of the complicated words and substitute them," Hadden says. "So what we do is provide an easy-to-understand explanation for the complicated words, and we use plenty of white space."

IRBs also could add bullet points instead of sticking to the header-and-paragraph format, Hadden suggests.

The typical informed consent form is too complicated in wording and how it appears. "You can provide a question-and-answer format with lots of white space," Hadden suggests.

Another strategy is to put the most important information first in the document because there is a fatigue factor when people read the forms.

"People don't retain things at the end of the form as much as they do in the beginning," Hadden says. "So make sure important information is first and put explanations where they make sense."

• Make changes to address low numeracy literacy. Informed consent forms express numerical information in multiple ways, and potential research participants might not understand what these mean. *(See story on health numeracy, page 31.)*

"If they don't understand a percentage, then give them a graphic," Hadden says. "We try to integrate all of these into our template."

Simplifying how percentages, ratios, and proportions are displayed can improve a study's enrollment, as well as its informed consent form, she notes.

"If participants don't understand the study's risks and benefits, then they'll be less likely to enroll in the study," she says. "If the study has complicated numbers, then the sample may be adversely affected." ■

Create More Thorough, Efficient New IRB Member Training

Educating and onboarding IRB members should include more than perfunctory online human subjects research training. The goal could be to provide new members with comprehensive information in a well-organized training program.[1]

At least one IRB has accomplished this goal through a combination of interest sessions, electronic education, in-person training, individual electronic submission system training, and mentoring.[1]

The IRB also has a new member handbook that summarizes information the IRB members will need, says **Meghan Wright**, MEd, MBA, IRB training manager at Virginia Commonwealth University (VCU) office of research in Richmond.

The following are some additional strategies for improving new IRB member training:

• Use interactive educational activities. The VCU IRB has a drag-and-drop interactive activity in which a board member can select one of the yellow highlighted bubbles, all related to potential reviewer notes, into a blue box with the appropriate criteria for IRB approval.

"It's a way for us to see whether they understand what they're learning," Wright says.

For example, one yellow reviewer note reads, "Please revise your informed consent documents to include more lay language." The corresponding criteria for approval box could be this: "Informed consent will be sought by each prospective subject or their LAR."

Another drag-and-drop sample is the yellow reviewer note that says, "Please explain how your subject recruitment will be representative of the population." This can be dropped in the criteria for approval box that reads, "Selection of subjects is equitable."

A third example is the yellow reviewer note: "Please describe who will have access to the encrypted data." The corresponding criteria for approval box would be this: "When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data."

• Follow up online training with

an in-person meeting. New IRB members could spend about eight to 10 hours, over a month if necessary, on their online instruction.

When they're done, they will meet with Wright to discuss how to perform a review and learn more about the IRB's electronic smart form.

"I meet with each person individually to go over the electronic submission system," Wright says.

After asking and answering questions, the new board member will meet with the IRB's quality assurance and quality improvement (QAPI) manager to go through an IRB review. The review was already conducted, and they can learn from recreating it.

"They're not actually reviewing it to make a decision on it, but the QAPI manager will walk through it with them," Wright says.

In-person training could take about three hours.

• Assign new IRB members to a mentor. "New IRB members complete their required paperwork, and then we assign them to a mentor," Wright says.

They can meet or communicate with their mentors on an as-needed basis. Together, the new member and mentor will review a first study and then complete a post-training evaluation.[2]

New member training is continuous, and having a mentor available helps with the transition to become a more seasoned IRB member.

• Make available IRB monthly educational sessions. The VCU IRB also provides training for researchers, including CITI training and regular, free sessions on human research protection topics and regulatory news, Wright says.

IRB staff and experts lead the midday sessions, which are attended by five to 50 people. IRB members also can attend the sessions, which have covered the following topics:

- Introduction to the IRB;
- Revised Common Rule: Single IRB;
- Revised Common Rule: Overview;
- Data Security and Records Management in Research.

• Solicit feedback on new IRB member training. New IRB members complete a survey about the training experience, the format, organization, their level of preparedness, and other topics.[1] They rank their experiences on a scale of one to five, with five being optimal. So far, the average response is 4.8 out of 5.[1] ■

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Ethical Challenges of Social Research in the Digital Age

As we leave the analog age and enter the vast expanse of digital "big data," the potential benefits and risks for social science research are uncharted. The power for good use of aggregated ever-expanding data sets is unprecedented. However, this bright future casts a shadow as big data raises the specter of ethical breaches of informed consent and violated privacy.

The author of a new book on this challenge calls on social science researchers to take ethical responsibility for their studies, reminding them that IRB standards should be viewed as the minimum parameters.

"The IRB is a floor, not a ceiling," says **Matthew J. Salganik**, PhD, a sociologist and researcher at Princeton (NJ) University. "In many cases, it is the researchers themselves who have the most knowledge about the risks — both how those risks can be mitigated, and how the benefits can be maximized. I think that researchers should not stop once the IRB approval has been granted. They should continue to try to improve the ethical balance in their work."

As an IRB member at Princeton, Salganik encourages medical ethics boards to welcome participation by social science researchers.

"Researchers have an opportunity and an obligation to think about the ethics of what they are doing, beyond just what the IRB requires," he says. "I think most researchers do that, particularly in computational social science and big data. The researchers

often have more awareness than the IRBs about what is possible and what is a potential risk. It's unreasonable to expect the IRBs to have more technical expertise than the actual researchers. There has to be a role for the researchers themselves in this process. I think IRBs should encourage that."

Many of these issues are explored in Salganik's book, *Bit by Bit: Social Research in the Digital Age.*[1] We asked him whether big data research has the potential to lead to the kind of disastrous, unethical studies that have long been the bane of human research.

"Absolutely — I mean, people are people," he says. "Those in the past have done unethical things, and they could certainly do them in the present and future. Some of the risks have changed a little, but I certainly think it is possible for those kinds of things to happen. IRBs are important."

Some of the digital data risk may occur beyond the range and oversight of IRBs, but hopefully the knowledge base of ethical research can be brought to bear on such situations.

"It's also relevant to separate researchers from governments," he says. "Some people are unhappy with the way that large companies and governments surveil people and their behavior and build enormous databases. That poses a number of questions that are beyond the scope of the IRB. Maybe some of the ideas that IRBs have developed could help companies and governments with how to use their data responsibly outside of the settings that are covered in the Common Rule."

Salganik opens his book with a seemingly innocuous example of a cellphone survey in Rwanda, where researchers called people to ask their demographic and social characteristics. The study took a digital leap when the researchers integrated the survey data with the call records of all customers of the mobile phone provider. Crunching the data in a computer model, they developed a method to predict a person's income and economic status by their call records, creating a map of wealth distribution across the African nation.

Given the possibilities suggested by this relatively benign example, it is understandable that Salganik dedicates a full chapter in his book to ethics and social science research. At first glance, digital aggregated data sets would seem to lend themselves to sharing information and ease reproducibility, a common want in the clinical research world.

"On the one hand, the capabilities of the digital age definitely make it easier to transmit and store our data and our code, and make it easier for other people to run our code," he says. "But obviously, some of this data is not sharable for privacy reasons. Some of this data is owned by companies, and some of it is potentially very personally identifiable."

The technical infrastructure to share data is increasing, but there will continue to be questions about deidentifying research subjects and ensuring they give informed consent.

"I think there is going to be an increasing role for third-party oversight," Salganik says. "It helps decrease the chance of a bad outcome. It also helps build confidence in the public and promote best practices. Again, these are really hard, complicated issues. The idea of having [IRBs] that have seen many of these things before and can offer guidance — that is potentially a very helpful thing that a lot of researchers would want."

To assist in this effort, social science researchers should consider drafting an "ethical appendix" to track and report issues as they arrive in a supplement published with the article. Suggesting that researchers begin this effort before their study begins, Salganik explains in his book that this exercise is designed, in part, to "force yourself to think about how you will explain your work to your peers and the public. If you find yourself uncomfortable while writing your ethical appendix, then your study might not strike the appropriate ethical balance."

While this ethical diary of sorts may help the researcher during the study, publication of these appendices with the research could inform decisions when such issues arise in subsequent trials.

"The decisions that we have to make about the ethics of using big data are very complicated," he says. "Right now, there are a lot of ethical discussions happening among researchers that are not written down. Researchers do not necessarily feel there is a venue to include that. For a researcher, writing an ethical appendix can help clarify your own thinking. Also, it can help you clarify your thinking to other researchers who are facing similar challenges."

IRBs who find this idea intriguing could encourage researchers, but the process may be more effective if there is no attempt at perfection, he says.

"No one is going to argue that these ethical appendices are some final, perfect handling of a situation," he says. "It is more like, 'These are the ethical issues I thought about, here are the steps I took, and here is what I decided to do.' If other people have a better way of thinking about it and can do it better — great."

Such open discussion can improve social research design and digital data protection. Salganik envisions social

research marked by ongoing assessment and communication, a continuum that moves away from the more dogmatic, binary view that something either is ethical or it is not.

"If we think of ethics oversight as checking boxes to get IRB approvals, we are all missing some important opportunities," he says. "As researchers, we are missing the opportunity to make our studies safer and more beneficial and more ethically well-balanced. I think as IRBs, we are also missing the opportunity to make suggestions to help improve the study. One way to think about it is that no matter what we're doing, it could probably be better."

Opening this ongoing dialogue is a nod to "intellectual humility, which is appropriate in the face of difficult ethical challenges," he wrote. This is something of a Socratic approach, where the reward of wisdom is asking the next question regarding the unknown.

"It reminds us how there are no easy answers to these issues," he tells *IRB Advisor*. "People who want easy answers to the ethics of big data research are going to be disappointed. But that doesn't mean we can't make progress. In fact, we can make a lot of progress by building on existing ethical principles, like the Belmont Report." ■

REFERENCE

1. Salganik MJ. *Bit by Bit: Social Research in the Digital Age*. Princeton University Press. Princeton; Oxford 2017.

Unique Informed Consent Challenges if Research Participant Is Incarcerated

It is well-established that incarcerated people suffer disproportionately from low literacy and health-related conditions that can affect cognition. Despite this, modified informed consent processes are not required by federal guidelines.

"The prison system in America is deeply, profoundly, unfixably unethical. How you do ethical research in such a system is always a quandary," says **Nancy Neveloff Dubler**, senior associate at the Montefiore-Einstein Center for Bioethics and professor emerita of bioethics at the Albert Einstein College of Medicine, both in Bronx, NY. Dubler co-authored *The Ethics and Regulation of Research with Human Subjects*.

Prisoners arguably can provide consent to research in the same way they provide consent or refusal of medical care. "On the other hand, if the inducements are very great, it's an unfair position to put the inmate in," says Dubler, noting the long history of unethical research practices involving incarcerated subjects. "Prisoners were used to test and develop random things, and would be promised a better place to live or better food," says Dubler.

The Common Rule was designed to prevent such research. The regulations permit only certain types of research on prisoners, including:

- research that is solely the study of the possible causes of incarceration and of criminal behavior, provided that the study presents no more than minimal risks and no more than inconvenience to the subjects;
- research on prisons as institutional structures;
- research on conditions particularly affecting prisoners as a class, such as drug addiction or vaccine trials for hepatitis;
- research on practices of innovative or accepted interventions that have the intent or probability of improving the health of the subject.

"This means that you can't use prisoners to test new drugs simply because they are useful, you know where they are, you can come back to them, and they're convenient," says Dubler.

Drugs being tested have to, in some way, relate to the population that is being studied. For example, anonymous surveys of one detoxification unit revealed that over half of inmates were HIV-positive, says Dubler: "Clearly, this was an issue that you could study in the prison population, with proper safeguards."

However, in a prison setting, it's not possible to distinguish between refusal of care and denial of care, says Dubler: "It's a very complicated setting in which to provide care, which makes it a super complicated setting in which to do medical research. The other problem is that prisons are basically untrustworthy settings."

When someone does not show up for an appointment, researchers have no way of knowing if it's because that person chose not to come, or whether a guard prevented him or her from coming. "Prisons are not places of transparency, and they're settings in which prisoners are used often to their own detriment, but sometimes for their benefit," says Dubler. "This makes it a quite complicated area."

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Mitigating potential conflicts of interest is a thorny ethical challenge if research participants are incarcerated.

"It's possible that the researcher, the researcher's university, and the correction facility are all funded by a single source," says **Alina Bennett**, MPH, PhD, a postdoctoral fellow at McGovern Center for Humanities & Ethics at University of Texas Health Science Center at Houston.

Bennett offers a hypothetical to illustrate the complexity of conflicts of interest. A highly infectious agent, "Hepatitis Z," is quickly spreading among certain prison populations who share a behavioral exposure. If left untreated, it can cause liver failure or hepatocellular carcinoma. A significant percentage of inmates are infected, despite the fact that the virus is almost nonexistent in the general population. While the standard of care is a liver transplant, this is not financially feasible in the prison setting.

In this scenario, a researcher at a state-sponsored university working on a potentially curative therapy approaches the institutional review board seeking approval for a prisoner-only study. This researcher believes that prisoners are suffering from this virus's complications at much higher rates than others and thus, the study ought to prioritize therapy for inmates over therapy for nonincarcerated people.

"On the face of it, this situation might not ring any alarm bells," says Bennett. "However, an inherent conflict of interest exists concerning what is responsible for the problem and what is responsible for the solution."

One issue is that the state bears responsibility for prisoners being exposed to the virus in the first place. The state also benefits from access to a relatively static pool of human subjects who are newly diagnosed, yet are denied the standard of care by the state. Lastly, the state stands to benefit from the development of a drug should the trial be successful.

"Because the state will benefit both during the study and potentially after its completion, the ethical justifiability of this work hinges on the successful efforts of the correctional facilities to stop the creation of newly eligible human subjects for this state-run trial," says Bennett.

Simple disclosure is not sufficient. In this scenario, securing a person's informed consent requires a two-step process.

"The first step is that the study team must recruit decision scientists," says Bennett. Decision science is a growing field that focuses on supporting patients facing complex decisions. The consent process must inform patients about not only the study, but also the relationships between the state, the researcher, the institution, and the correctional facility.

"Participants must understand that an entity might benefit from a successful discovery — which was made possible because the entity did not honor their obligation to protect prisoners from infectious diseases," says Bennett.

The second step is to design a decision aid. The decision scientists will assess the decision that is facing potential study participants, and will create an evidence-based decision aid that meets — and far surpasses — all federal guidelines concerning consent. "These aids can take a variety of forms, such as an iPad application, a webpage, or a document," says Bennett.

Lastly, knowledge checks are performed during the use of the aid, and afterward.

"These conversations take a neutral, nondirective tone, so that the patient will remain free of influence as they make an informed decision," says Bennett. ■