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INSIDE

RELIAS MEDIA

SACHRP Approves Participant Payment Guidelines

Calls on OHRP and FDA to clarify several key issues

By Gary Evans

The Secretary's Advisory Committee on Human Research Protections (SACHRP) recently approved guidelines on paying research participants, addressing a range of issues from "token" payments to frank coercion.

"The idea behind this was to really amplify some of the existing guidance because we know that IRBs have a wide variety of perspectives on what kind of payments are appropriate for subjects. One of the concerns is whether paying subjects to participate in clinical trials is unduly influential," said SACHRP member **Nancy King**, JD, who outlined the draft guidelines before the panel at a July 30-31 meeting.

> "WHAT WE'RE FOCUSING ON IS WHETHER THE AMOUNT OF PAYMENT SEEMS TO BE SUCH THAT IT IMPEDES PARTICIPANTS' ABILITY TO MAKE GOOD DECISIONS ABOUT THEIR PARTICIPATION."

After considerable discussion into the ethical implications of paying subjects too much or too little, SACHRP approved the guidelines, entitled "Addressing Ethical Concerns Regarding Offers of Payment to Research Participants." The guidelines had not been published as this report was filed.

The background cited in the draft is that in January 2018, the FDA updated its Information Sheet[1] regarding payments to participants. Part of this was to clarify that the FDA does not consider reimbursement for travel and lodging at a research site to be an "undue influence" on the decision to participate.

"Other than reimbursement for reasonable travel and lodging expenses,

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IRBs should be sensitive to whether other aspects of proposed payment for participation could present an undue influence, thus interfering with the potential subjects' ability to give voluntary informed consent," the SACHRP guidelines stated. "[The committee] has been asked to consider whether there is a need for additional updates to guidance related to payments that go beyond reimbursement of participant expenses."

The Office for Human Research Protections defines undue influence as potentially occurring "through an offer of an excessive or inappropriate reward or other overture in order to obtain compliance," in the guidelines.

"Because influence is contextual and undue influence is likely to depend on an individual's situation, it is often difficult for IRBs to draw a bright line delimiting undue influence," SACHRP stated in the guidance. "Although undue influence and coercion are often discussed together, this document focuses primarily on undue influence because genuine offers of payment do not satisfy the definition of coercion."

SACHRP also focused on payment to "decisionally capable adults" offered in IRB-approved research at all risk levels, including research with and without potential direct benefit to participants. The guidelines try to provide IRBs "with a few more tools" to help determine when payment is appropriate and when it may be unduly influential, King said. It is in avoiding the latter that IRBs may think "it is better to be safe than sorry" and minimize or prohibit payments.

"Our approach is that this is kind of like killing a fly with a sledgehammer," King said. Instead, SACHRP seeks to break down the types of patients and offer insight on those that raise concerns about undue influence and those that clearly should be permitted.

Coercion was defined for the purposes of ruling it out of the discussion, as it implies pressures that would be inappropriate in a human research concept, King explained. "Coercion entails a threat to violate someone's rights or fail to fulfill an obligation to him or her in order to obtain compliance by creating a circumstance in which the person has no reasonable alternative but to comply," the guidelines stated.

Elaborating on this point, King said "coercion is a different concept and doesn't really apply in the payment situation because generally speaking, offers aren't coercive, but they may be unduly influential."

As defined as a "jumping-off point" in the guidelines, undue influence generally entails an "excessive offer … that leads to poor judgment or a compromised decision-making process." The resulting decision could lead to participant harm, but undue influence raises ethical questions even if no harm is likely to result.

"IRB approval of research should play an important role in minimizing the likelihood of adverse outcomes and promoting effective consent processes," the guidelines stated. "Thus, SACHRP takes the position that payment raises concerns about undue influence when it appears likely to inhibit potential participants' adequate consideration of and reflection about important study features, such as risk, burdens, and discomforts, and impair their understanding of the research and their participation in it."

"What we're focusing on is whether the amount of payment seems to be such that it impedes

participants' ability to make good decisions about their participation," King said.

Five SACHRP Recommendations

The committee guideline addressed these issues in five recommendations, beginning with agreement that reimbursement payments do not raise concern about undue influence:

Recommendation 1: SACHRP agrees with and recommends that OHRP adopt the stance on reimbursement payments described in the 2018 FDA information sheet "Payment and Reimbursement to Research Subjects."

"For example, you go someplace to participate in a study and they pay for your parking," King said. "Well, that shouldn't raise concerns."

The SACHRP guidelines recommend a broad interpretation of reimbursable costs, although noting that lost wages are probably better viewed as a matter for compensation.

The panel defined "compensation" as payment for the participant's contribution of time and acceptance of research-related burdens and inconvenience, as distinguished from the out-of-pocket costs addressed through reimbursement.

Recommendation 2: SACHRP recommends that OHRP and FDA clarify that compensating participants for their time and effort is not an undue influence.

"Some individuals may have to forgo other sources of income as a consequence of spending time in research," the guidelines stated. "Compensation at least makes up for some of the financial difference between research participation and other activities. Thus, in these cases, there is no reasons to be concerned that compensation payment would compromise decision-making," according to the guidelines.

Although compensating participants for time and effort does not necessarily raise concerns about undue influence, it does spur a few immediate questions, King said. "The question then arises: How do you determine what counts as fair compensation?" she said. "Is it an hourly wage? Is it proportionate to the income of the person participating?"

King favored the analogy of jury duty, while saying perhaps research compensation should be somewhat more than typically paid for that civic duty. "The idea is that a modest compensation, which the IRB can calculate in appropriate ways, should not actually raise concerns about undue influence," she said.

Recommendation 3: SACHRP recommends that OHRP and FDA acknowledge that appreciation payments to research participants do not raise concerns about undue influence.

"A category that I particularly think is important is 'appreciation' payments because many who participate in research studies are hospitalized or undergoing treatment at the same time, and reimbursement and compensation are not needs for them," King said. "[Appreciation] payment is an acknowledgement of the contribution subjects are actually making. It makes sense to regard payments of appreciation, which are usually rather small, as not raising concerns [of undue influence]."

Recommendation 4: SACHRP recommends that OHRP and FDA clarify that incentive payments may raise concerns regarding undue influence in some cases.

"Incentive payments go beyond what participants may be owed as a matter of fairness," King said. "They are designed very often to ensure rapid and adequate enrollment into a trial and may raise concerns."

To illustrate this point, the SACHRP guidelines included two different prospective participant scenarios:

Prospective participant 1, whose reasoning about enrolling in an IRB-approved study goes as follows: "If the payment were not so high I probably wouldn't do this. I've thought carefully about the risks and benefits, asked questions about them, and understand … Still, the risks worry me. But I need the money, so I'm going to say yes."

The SACHRP guidelines concluded, "This participant has been influenced by payment, but not unduly influenced because she has not been asked to join an unreasonable study (assuming adequate IRB review) and because she is making an informed, understanding, and voluntary choice under the circumstances. Her conclusion that study participation is her best available alternative to make money does not make it involuntary."

In contrast, prospective participant 2 sees the same study and reasons, "I am desperate for money, I don't care about the risks. I don't even want to know what they are, just sign me up so I can get paid."

Participant 2 has been unduly influenced by the offer of payment, the guidelines noted. "He, too, would be enrolling in a reasonable study, but payment has inhibited his adequate consideration of reasons for or against participation."

Participant 2 "is someone who has not spent enough time making what the IRB, or any of us, would consider a thoughtful decision about participation," King said.

The guidelines underscored this point, emphasizing that IRBs and investigators have an ethical and regulatory duty to support and encourage rational decisions by possible participants.

"Although individuals are free to make 'rash' or 'snap' decisions outside the research setting (for example, when accepting a job offer or making a purchase), IRBs and investigators must fulfill their responsibilities for rash participant protection, including assurance of adequate informed consent," the guidelines stated. IRBs can meet this duty through the overall process of evaluating the incentives, the thoroughness of the consent form, and the circumstances under which consent was given.

"IRBs need not monitor the enrollment process of each individual participant or account for their unique characteristics," the guidelines stated.

IRBs should not overreact to incentive concerns and simply cut or cancel payments, King warned. "What we would hope to do is ensure that these kinds of participants are provided with opportunities to be more thoughtful about participation," she said. "Simply saying 'let's lower the amount of payment' raises a certain set of practical and theoretical problems. It may make enrollment difficult. It may actually ensure that the only people who enroll are people for whom any amount of money is important, and that kind of seems unfair."

Recommendation 5: SACHRP recommends that OHRP and FDA acknowledge that concerns about incentive payments that may be unduly influential can be managed without necessarily lowering or eliminating them, and provide guidance regarding how to minimize the possibility of undue influence.

To avoid these pitfalls, IRBs should encourage investigators to adopt approaches that will support high-quality decision-making. "Make sure it's a process using teach-back comprehension methods to encourage potential subjects to think and reflect on aspects of the study," King said. "Incorporate waiting periods and other kinds of support for those people who say, 'I just don't have a choice. I need the money.'"

"INCORPORATE WAITING PERIODS AND OTHER KINDS OF SUPPORT FOR THOSE PEOPLE WHO SAY, 'I JUST DON'T HAVE A CHOICE. I NEED THE MONEY.'"

According to the SACHRP guidelines, these approaches include:

- Setting aside sufficient time for knowledgeable study staff to review the entire consent form with potential participants and answer any questions, rather than permitting a passive consent process in which potential participants are expected to review materials on their own;
- Including tests of comprehension or teach-back methods could provide an indication that potential participants are aware of and understand key information about the study;
- Incorporating a waiting period for potential participants to reflect on their desire to participate and potentially discuss the study with trusted others;
- Considerations that prospective participants' current interest may conflict with their future interest (for example, asking for reflection of the value to the individual of trading payment for risk that may materialize into harms later).

Overall, the SACHRP committee called for more guidance from the FDA and OHRP on participant payment issues, reiterating concerns that IRBs need help managing undue influence and incentive payments without resorting to King's "sledgehammer."

"There are additional considerations, such as timing of payment, that are important," King said. "We know if you say 'you will get all your money at the end of the study' that could encourage people to stay in a study past the point they consider to be safe for themselves."

SACHRP recommends prorated payments, noting that a study completion bonus could be appropriate.

In a flurry of last-minute wordsmithing, there was an effort to remove the term "token" payments in favor of "appreciation" or other less-loaded adjectives.

"They're generally minimal, but we called them 'token' payments to begin with at early points and I don't like that. I think it's dismissive," said **Stephen Rosenfeld**, MD, MBA, chairman of SACHRP.

(Editor's note: Video of the July 30-31 SACHRP meetings can be viewed online at: https://bit.ly/2kFFB7O.) ■

REFERENCE

1. U.S. Food & Drug Administration. Information Sheet. Payment and reimbursement to research subjects: Guidance for institutional review boards and clinical investigators, January 2018. Available at: https://bit.ly/2m1BnYo. Accessed Sept. 11, 2019.

'Re-Consent' a Gray Area for IRBs

SACHRP tries to answer OHRP questions

By Gary Evans

Wading into a thicket of ethical and legal issues, SACHRP is trying to clarify the concept of "re-consent" and when is it necessary.

In roughing out a draft at its July 30-31 meeting, the committee cited the following question presented to them by OHRP: "When new information requires revisions to the informed consent document for research that was approved under the pre-2018 Common Rule, is it necessary to transition a protocol and informed consent to the revised rule when the new information results in a change in the consent document?"

The committee's answer: "SACHRP recommends that the provision of new information to research participants should not require a protocol to transition to the revised rule. When an informed consent document that was approved under the pre-2018 rules is revised, it should continue to be grandfathered under the pre-2018 rule."

That seems clear enough, but other scenarios and contingencies soon clouded the discussion. For instance, does discovery of a new risk in an ongoing trial trigger the need to re-consent everyone? How would that scenario work in terms of transitioning it to any applicable provisions in the new Common Rule? SACHRP discussion diverged on this point, with some members noting certain consent forms are updated over minor changes and others warning not to err on the side of more paperwork.

"There's no question about the ethics of giving people information," said **Stephen Rosenfeld**, MD, MBA, chairman of SACHRP. "There's a given that new information that might affect participation or willingness to continue needs to be shared. The question is really a mechanistic one: How you do that? Is it a rewrite of the consent form? Is it a consent addendum? Can you call people and record it in the study record?"

> FROM A STUDY PARTICIPANT'S PERSPECTIVE, SIGNING FORMS AND RE-CONSENTING IS A BURDEN THAT SHOULD NOT BE PUSHED FORWARD WITHOUT SIGNIFICANT CAUSE.

From a study participant's perspective, signing forms and re-consenting is a burden that should not be pushed forward without significant cause, said **Janet Freeman-Daily**, MSc, ENG, a former clinical trial participant who serves as a patient advocate on the committee.

"I think there's an ethical consideration for respect for persons," she said. "If what is getting changed is not going to have any scientific impact, I don't care. If it's not going to affect my rights, I don't care. In my clinical trial, first it was every two weeks, then four weeks, then eight weeks, I got to spend 20 minutes with my expert doctor. If I have to spend 10 minutes of that time signing documents that have no impact on me whatsoever, you're not respecting my time. I think that I would like to see a positive step toward saying that if this is not going to impact this person's perception of their rights or their risks in the trial, just give them a piece of paper and let them initial it and let that be the end of it."

Speaking for the committee, Rosenfeld said most probably agreed on the point, but it could not be framed that forcefully in the draft document, which remains under development. "I think there's pretty much universal agreement with that, but we did not frame it that positively because we wanted to sort of give people the choice for institutional policy and such, but that's something we should consider — particularly from that perspective," he said.

With some acknowledgement of these various potential entanglements, the document drafted by SACHRP gives IRBs options to address the issue on what will likely be a case-by-case basis.

'As Flexible as Possible'

"Where we came down as the [SACHRP] subcommittees on this is that it should be as flexible as possible. That's what the document reflects," said **David Forster**, JD, co-chair of the SACHRP Subcommittee on Harmonization.

Forster gave an overview of the draft document, which underscored the bedrock principle of informed consent but also states that "re-consent" is a term more colloquial than clinical.

"The process of informed consent occurs when communication between a potential participant and a researcher results in the individual's authorization or agreement to participate in a research study, or their refusal to participate," the SACHRP draft document stated.

In some research studies, circumstances arise in which new information becomes available and needs to be shared with participants who have consented to the trial. "OHRP has asked the SACHRP subcommittees to comment on circumstances in which participants already enrolled in a study should be provided with relevant new information and have the opportunity to either withdraw from the research or to affirm and document their willingness to continue in the research," the draft stated. "In the research community, this process is colloquially referred to as 're-consent.'"

Neither the Common Rule nor FDA regulations use the term re-consent or describe a process for providing new information to participants who already are enrolled in a research study. There is a provision about reporting "significant new findings," the draft states. "However, providing new findings is not the same as asking an individual to review their consent to participate in research and confirm their willingness to continue participation."

Potential Approaches

While IRB approaches for renewing informed consent over the course of a research study vary, there are a few commonly used pathways.

"Frequently, sponsors, clinical research organizations, and investigators submit a revised consent document with an accompanying recommendation of reconsent for all enrolled participants," SACHRP stated. "However, data are lacking regarding what ultimately happens with that request. Do IRBs question whether reconsent is required or do they accept the request and approve the proposed process?"

Facing this conundrum, the committee cited the following possible approaches for providing new information to research participants:

- Require researchers to repeat the informed consent process with the revised informed consent document(s), and document consent following the requirements;
- Require that researchers present the new information using an addendum to the original informed consent document and either obtain documentation directly or describe the communication process in the participant's research records;
- Allow researchers to orally communicate the new information and document that communication.

"How additional information is communicated will depend on many factors, including the type of study, the complexity, and/or urgency of the new information and the research population," the draft stated.

There also is information that does not have to be communicated to participants, such as changes to the inclusion criteria that have no effect on those already enrolled. With the revised Common Rule, OHRP reopened questions on a matter that has heretofore been handled by a wide variety of approaches.

"I have to say that from my IRB experience we talked about this, but it was never a problem in the context of individual protocols," Rosenfeld said. "We could always calibrate the amount of information and ask for an addendum vs. an update to the consent form — there were lots of ways to do it. I don't think it was perceived as a problem. That being said, there was no standard way. I'm sure every IRB did it differently. That's the context. Once we started to dig [into this] there was more there."

(Editor's note: Video of the July 30-31 SACHRP meetings can be viewed online at: https://bit.ly/2kFFB7O.) ■

In New Common Rule Era, There Is Role for Post-Approval Monitoring

PAM works for large and small IRBs

By Melinda Young

Post-approval monitoring (PAM) is one method that IRBs could employ when keeping tabs on minimal-risk studies or studies that no longer have to go through the continuing review process. It also can be a way for a small IRB to improve office efficiency and enhance relationships with investigators.

The new Common Rule says that continuing review no longer is required if:

- the research is eligible for expedited review;
- the research is subject to limited IRB review;
- the research was approved by the full board, but has progressed to where it only involves data analysis, even if the information or biospecimens are identifiable,
- the research was approved by the IRB, completed, and now only includes accessing follow-up clinical data from clinical care procedures.

IRBs that would like additional information from studies, after continuing review ends, could use PAM to obtain that information.

For example, one small IRB began providing PAM of minimal-risk studies that underwent expedited review. A larger research institution's IRB used PAM as an alternative to continuing review, says **Cecilia Brooke Cholka**, MA, CIP, IRB specialist at the University of Nevada, Reno. Cholka is scheduled to speak about PAM at the Social, Behavioral, and Educational Research (SBER) Conference at the 2019 Advancing Ethical Research Conference, Nov. 17-20, 2019, in Boston.

Once an IRB develops PAM tools, including an initial email sent at the first of the month, IRB staff might realize how helpful PAM is in terms of education, Cholka says.

As part of PAM, an initial email to investigators, such as the one Cholka has noted, could include some simple "yes" and "no" questions, including these examples:

- Did any protocols deviate during the project?
- Has the funding source changed?
- Were there any unanticipated problems? Were these reported to the IRB?
- Have any participants complained about the study?
- Are all research team members trained? Have they met conflicts of interest requirements?

Email Follow-Up Can Help

Many institutions are not comfortable with eliminating all post-approval review of expedited studies. Starting a PAM program provides a middle ground, says **Andrea Rossing McDowell**, PhD, IRB administrator and business communication lecturer at Seattle University. McDowell also is scheduled to speak at the SBER conference in Boston.

"What we do now for all expedited studies is write to them and ask investigators, before the year is up, to answer a few questions," she says. "The email asks if they have concluded the research project and if they have concluded data collection and are just doing analysis, and then we will downgrade those to exempt status — if they are not dealing with human subjects."

The email references federal regulations and explains that the questions are in lieu of a formal continuing review process. It says, "We are checking in briefly to determine the current status of your study," according to a sample email Seattle University shared with *IRB Advisor*.

The email also asks five questions about the study, including whether the research project has concluded or concluded all data collection. Here are two sample questions:

- "If your study is ongoing, approximately when do you anticipate concluding data collection?"
- "For student studies, please indicate whether any data remain identifiable, and if so, whether raw data were transferred to the faculty advisor."

The email also reminds investigators to fill out the modification request form if they wish to make any significant changes to an ongoing study.

Seattle University received far more expedited review and exempt studies than full board review studies, she notes. "We didn't have any full board reviews last year, and we typically have two to five full board reviews, so last year was unusual," McDowell says.

"For full board protocols, where there's a slightly higher risk level, we do a continuing review with those and have a brief continuing review application that asks about the status of the project," McDowell explains. "Any project, previous to last year, that's still ongoing and was a full board review, still needs to have a continuing review."

But since the new Common Rule was implemented, the IRB has seen more expedited reviews, she notes. Prior to the Common Rule change, expedited, minimal-risk studies were awarded a two-year approval period.

"They wouldn't have to keep checking with us every year if there were no adverse events or problems that occurred," McDowell says. "Most of our researchers concluded their studies before that two-year period ended."

Find Tools and Models That Fit

For larger IRBs, post-approval monitoring can employ a variety of tools and models. Cholka, until her recent IRB role at the University of Nevada, worked for an IRB that had conducted for-cause audits before the new Common Rule eliminated continuing review for many studies. "We were flustered because it felt like a really important thing that was taken away," Cholka says.

IRB members were uncomfortable losing sight of projects and wanted to ensure appropriate conduct of ongoing research. They researched models that would work in this new environment, she adds.

"The criticism of continuing review is that it's just filling out paperwork, it's an administrative burden, and it's not needed anymore," Cholka says. "But without it, you don't know what's going on."

That is why the IRB decided to create a PAM program with several different parts, varying in depth. *(See list of potential PAM models, page 117.)*

PAM provides a good opportunity for IRBs to engage with researchers through outreach and ongoing education about regulations and requirements, she notes. "It helps increase an IRB's visibility and builds its reputation as a collaborative worker, instead of casting the IRB as adversaries," Cholka says. "It broadens our mission to one of saying, 'Here are the different tools to help you do it right, and we're here to help you.'"

"IT BROADENS OUR MISSION TO ONE OF SAYING, 'HERE ARE THE DIFFERENT TOOLS TO HELP YOU DO IT RIGHT, AND WE'RE HERE TO HELP YOU.'"

For example, IRBs could develop a minimal PAM model that involves giving researchers a self-assessment tool that serves as a reminder of their patient recruitment, screening, recordkeeping, and informed consent responsibilities. Sample questions might include the following:

- "Are all IRB records, including consent forms, correspondence, protocol, signed applications, and an approval letter, stored in an accessible location for at least three years after the project is closed?"
- "Do you have documented approval of advertising and recruitment materials?"
- "Did you use IRB-approved script/text to enroll participants?"

The Seattle University IRB's PAM model asks investigators for brief answers to its email questions about the study's status: "We ask, 'If your study is ongoing, please tell us in no more than one sentence what the current status is,'" McDowell says. "They can answer 'yes' and 'no' to most questions and then give a brief update that we'll save to their protocol file."

Using a brief check-in email has helped improve compliance, resulting in 100% of people responding. Under the continuing review process for minimal risk studies, the IRB would have to pester researchers to fill out the required form and submit it to the IRB, McDowell says.

"Even though it is a short form, people get busy doing other things," she explains. "But in the first two weeks of using the email system, we were able to close out 20 studies because investigators could just respond by email."

It's also a big plus from a recordkeeping perspective, she adds. "It takes very little effort on our part and on their part, and our records are far more accurate now," McDowell says.

The email PAM process works especially well with studies involving student researchers, she adds. When students are the lead investigators of a study, all PAM ends with the student's graduation date. "Once they are alumni, we cannot provide oversight because they're not our students anymore," McDowell explains. "In the past, we'd never hear back from student researchers, and we'd have to track down their faculty advisors to find out what was going on," she adds. "Now, we send

the email prior to their graduating, and we get feedback from them, saying, 'Yes, I'm done, and I'm graduating,' and we close the student files."

If a student wants to continue a study after graduation, the IRB works with the faculty advisor, who becomes the study's lead researcher and the student is an affiliate, she says.

"For us, the post-approval monitoring, brief email system has made things much easier and has also improved our recordkeeping," McDowell says. "It's even improved our relationships with researchers because when they get an email of 'Hey, what's the status?' they're much more likely to respond, and we can say, 'OK, let's close this file.'" ■

Sample Models of Post-Approval Monitoring Programs

Some models are self-assessments

By Melinda Young

There are many ways IRBs could conduct post-approval monitoring (PAM) programs. These can range from simple email questions and answers to full reviews at the research site.

These programs often are designed to be educational, as well as adding a layer of accountability in the human research protection process.

"Once we developed post-approval monitoring tools, we realized what a good opportunity it is, in terms of education," says **Cecilia Brooke Cholka**, MA, CIP, IRB specialist at the University of Nevada, Reno. Cholka is scheduled to speak about PAM at the Social, Behavioral, and Educational Research Conference at the 2019 Advancing Ethical Research Conference, held Nov. 17-20, 2019, in Boston.

Cholka learned a great deal about post-approval monitoring when she worked to help develop various PAM models at prior institutions. She describes, from that experience, these sample PAM models:

• **Administrative check-in.** Projects that do not require continuing review can use administrative check-in. IRB staff send an email to the principal investigator (PI) to assess the status of the project. Questions in the email include:

- Is the project is still collecting data?
- Were there any adverse events?
- What are the unanticipated problems involving risk or protocol deviations?
- Are there are any new findings that may affect risk to participants?

One purpose of the email check-in is to remind PIs of their obligation to submit amendments and event reports.

• **Full on-site assessment.** For these studies, there would be a full assessment, conducted by IRB staff. The IRB professional would review research documents, interview researchers, and check the site's storage and other activities, comparing their practices to what the protocol described.

• **Self-assessment.** "This is where we take paperwork for the full audit and cut down its questions to make it a tool that researchers can use themselves," Cholka says.

The IRB sends the PI a self-assessment checklist to complete within a set period. Then, researchers return the self-assessment to be reviewed by the IRB.

• **Consent document review.** This is an abbreviated review that researchers can perform themselves, Cholka says.

Self-assessments could be limited to consent forms, or there might be some other limited scope to screen for potential quality issues. For a consent-only assessment, the IRB might ask the researcher to submit all signed consent/assent signature pages for all participants enrolled during a specified period.

• **Consent process review.** This review is conducted by the researcher. When a project is viewed as sensitive, high risk, or when the IRB expresses concerns regarding the process for obtaining informed consent, the IRB might request a consent observation of one or more participants. Researchers use a checklist to verify that the consent conversation contains all components.

• **Consent process observation.** "This is best practice for consenting participants," Cholka says. "The IRB looks at what it expects in terms of a good consent process."

Conducted by IRB staff, this

consent process observation takes place when a project is sensitive, high risk, or the IRB voices other informed consent concerns. Consent observation may be requested for one or more participants. Researchers are required to coordinate with the IRB for the observation.

• **Project team review.** Projects with large teams or special team training requirements could be selected for a project team review. The PI submits a project team form and training certificates. IRB staff verify that all team members meet training requirements and have signed a conflict of interest disclosure.

IRB reviewers assess studies to see which type of post-approval monitoring would be good for that study, Cholka says. After the reviews, the IRB sends researchers a letter of findings. "We always include what they're doing right because we're trying to make this a positive, collaborative experience," Cholka says. "We put in there, 'You are right on target with these things — you're doing exactly the right thing.'"

"When there are minor findings, the letter might say, 'We notice you said this; it should be this way, instead, and we recommend XYZ,'" she adds. "If there are major findings, we would generally escalate it to a full audit."

Feedback from investigators has shown that the PAM process is helpful, and it has given the IRB and reviewers a better understanding of studies' actual progress, Cholka says. PAM also helps improve education, outreach, and research protection, she adds. ■

Tips for Including Plain Language in Informed Consent Form

Communicate clearly, simply

By Melinda Young

Many informed consent (IC) forms fail to communicate simply and clearly. They might use language prospective research participants may not process easily.

While the new Common Rule provides some suggestions for making informed consent documents more readable, there are additional steps IRBs and researchers could take to improve the forms, including incorporating plain language.

Avoid Long Paragraphs, Jargon

Plain language is communicating clearly, with the goal of giving information to subjects in a way they can understand, says **Sean Horkheimer**, JD, CIP, regulatory chair at the WCG — Western Institutional Review Board (WIRB) in Puyallup, WA.

To improve informed consent with plain language, Horkheimer offers these tips:

• **Use common words.** IRBs and researchers need to adjust the language based on a study's intended participants. For example, a study might use the word "tachycardia." Many laypeople might not know what this means, so add a lay definition after the word, such as "rapid heart rate," Horkheimer says.

Keeping the language at a lower reading level is especially important for online studies, he notes. With online studies, there won't be anyone to sit with the participant to go through the form and answer questions, Horkheimer says.

"For an online study, I'd want to see if the clear purpose statement is written so that subjects understand the purpose of the research," he explains.

Some internet survey studies might not be able to disclose the specific purpose because knowing this would color participants' responses. The informed consent should explain what a subject will experience when enrolling in the study, and do so in a way that will make sense, he adds. Some online studies use language they might put in a grant application, and this is a mistake, Horkheimer says.

The biggest risk of online surveys often is the risk that confidentiality would be breached, he notes. "I would expect to see descriptions of the risks in plain language," he says. "They can say that the study will be anonymous, and they won't record the person's name and IP address."

One of the obstacles to plain language is familiarity. Researchers and IRBs are familiar with words like "randomization" and "placebo," Horkheimer says. But subjects might not understand these words in that context. After using the

word "randomization," an informed consent document might define it as "by chance," or "similar to flipping a coin." The form also might explain that no person is deciding whether the research participant receives the investigational drug/device or a placebo, which is like a sugar pill or an inactive device.

• Organize the IC form in a reader-friendly style. "Try to have one idea per paragraph," Horkheimer suggests. "Make it several paragraphs rather than one long paragraph."

Break up information in useful blocks, such as one paragraph to describe the nature of the drug, another to discuss the screening process, and a third to talk about randomization, he adds.

"If I had to give one tip for investigators who have finished writing their protocol and are ready to draft the consent form, it would be to ask the IRB for an informed consent template," he says. "The template is a good starting point that will make sure all regulatory elements are covered."

The template also organizes informed consent information and is valid. "IRB templates have structure and language that covers a lot of the regulatory material," he says.

By using the template, investigators also refrain from creating an IC form that just copies and pastes directly from the protocol, Horkheimer notes. "The language in the protocol is for a different audience, and it's usually read by someone with a scientific background, who is evaluating it from that perspective," he explains. "It's better to start fresh and come up with language that is direct and will cover the subjects, focusing on what the participants are concerned about most."

For example, a protocol might include language about the mechanism of an investigational drug and what it does in the body. Most research participants would be less concerned about how the drug works and more interested in learning how it is administered, he adds.

Another method of organizing the IC form is to balance the white space, avoiding walls of text, Horkheimer says. "If a reader sees a wall of text, the reader might have a defeated attitude. It's easier to read if there is one paragraph at a time, and it feels less like a hurdle," he explains. "If you think about the everyday experience of reading companies' terms and conditions, there is this massive amount of text that people just scroll through."

Other organizational methods include:

- Use headings as guideposts;
- Emphasize important concepts, using bold, underlining, and italics;
- Include only the necessary information.

• Write in a conversational style. IRBs also can improve informed consent documents by using shorter sentences and a conversational writing style, Horkheimer says.

Some IC forms are written in first person, using "I, me" sentences, or in second person, using "you, your" sentences. "If you address the subject, it's easier for them to understand what's happening to them, so I like to see language like that in consent forms," he says. "Generally, second person is easier to read."

IC forms also might avoid math symbols, when possible. For example, instead of writing a ratio as 1:1, it is better to just say that half of the subjects will be in one arm of the study, and the other half will be in the other arm of the study, Horkheimer says. "For every person enrolled in the first arm of the study, there is another person in the second arm of the study, it's half and half," he says.

IRBs also ask researchers to create a summary that lists information most important to participants in the front of the IC form.

• Ask a nonscientist to read it out loud. Asking a nonscientist or research person to read the IC form out loud is a good way to identify complicated language.

"What are the nonscientist's questions? If the person is reading it aloud and is tripping over certain concepts, then it might be a sign that we need to make the form more understandable," Horkheimer says. ■

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CME/CE QUESTIONS

1. **SACHRP recommends that OHRP and FDA clarify that what type of payment may raise concerns regarding undue influence?**

   a. Lotteries
   b. Appreciation
   c. Incentives
   d. Coercion

2. **According to Nancy King, JD, what is a potential risk of paying participants at the end of a study?**

   a. They may drop out to work.
   b. Participants may stay enrolled despite adverse effects.
   c. Lack of compliance with study requirements.
   d. Some states consider the practice illegal.

3. **Under the new Common Rule's changes to continuing review, which is one of the four circumstances in which continuing review is no longer required?**

   a. The research is eligible for expedited review.
   b. The research is subject to full board review.
   c. The research was approved by the full board, but only has a few subjects remaining in the data collection phase.
   d. The research was approved by the IRB, is completed, and clinical data are available for use in additional studies that may need to contact original research participants.

4. **Other organizational tactics for creating informed consent forms that use plain language might include:**

   a. using bold text instead of regular text.
   b. being creative with headlines of legal or regulatory jargon.
   c. footnotes with definitions to all complicated jargon.
   d. only the necessary information.