**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.