IRB Member Tip Sheet: Informed Consent Readability Pre-Review

The ***Partnership for Informed Consent Optimization (PICO)*** strives to improve the informed consent process at the NIH through: 1) a readability pre-review of the informed consent document(s) submitted with initial reviews (IRs), 2) a study-specific educational training on the IRB-approved informed consent process, and 3) observation of an informed consent discussion – in partnership with NIMH's Human Subjects Protection Unit (HSPU).

Why readability pre-review? According to the Milken Institute, "at least 88 percent of adults living in the US have health literacy inadequate to navigate the healthcare system and promote their well-being." Informed consent documents should be in a language, *and at a level,* prospective participants can understand. Our goal: 6th – 8th grade reading level.

PICO also strives to minimize therapeutic misconception and misestimation by avoiding the terms "treatment" when referring to investigational interventions, and "patients" when referring to research participants.

What is a readability pre-review? The readability pre-review is aligned with the OHSRP's office of Compliance and Training's ongoing *Improving Consent Form Readability Workshop* for NIH staff who write informed consent documents. Some readability pre-review concepts:

- Replace scientific terms with plain language ("injection" vs. "shot")
- Use active voice rather than passive ("We will take your temperature" vs. "Your temperature will be taken")
- Adopt conversational language ("We will ask you questions")
- Use short words, short sentences, and limit paragraphs to one topic
- Break up dense blocks of text with white space, tables, or bullets
- Use pictures to describe complicated concepts
- Sparingly utilize bright color or bold text to highlight important points

We also consider the expected study population. Long-time cancer patients will likely understand "restaging" and "PET/CT," but an explanation in lay terms will benefit prospective participants who are newly diagnosed.

How does it work? For certain studies, we revise one or more consents submitted at IR, and the IRB Analyst sends our edits/suggestions to the study team with the usual pre-review stipulations (stips). Study teams will accept, reject, or modify the suggested edits and resubmit the consent when they address all other pre-review stips.

PROTECT does not show tracked changes, so you won't see the edits or comments in the consent you review for the IRB meeting. However, we will summarize the review under the History tab, in the "Pre-review submitted" section. See item #6, "Note," which will include a summary of our review. Here's an example:

> *Note to IRB members pre-review edits of consent: This consent was initially submitted with Flesch-Kincaid Grade Level of 10.3, with over 35% passive sentences, which can be hard to read. The PICO pre-review lowered the Grade Level to 9.5 from Key Information through "Options" paragraph, but did not edit every line. We requested that sentences be shorter, more direct, and more conversational. Study team was then asked to re-submit consent with similar edits throughout the rest of the consent document (template language excepted). We requested they attempt to reach our goal of Grade Level 6-8.*

You can also compare consents using the document history in PROTECT, to see the changes after re-submission.

What does this mean for IRB Reviewers? Fewer stips. Less editing, particularly during IRB meetings.

On occasion, the IRB has added complicated or scientifically specific language back into the consents after we have already simplified the language and obtained study team concurrence. Please follow the 95% rule. Your edits should be substantive, should benefit the participant, or should correct things that are wrong.

If you do edit the consent documents:

- Please edit during your pre-meeting review, not during IRB meetings.
- Tell the IRB Analyst early on if you have substantial edits or feedback.
- Make any edits with "track changes" turned on and upload that version with your review comments in PROTECT.

Questions about the *Partnership for Informed Consent Optimization* may be directed to Chris Witwer CIP, OHSRP Policy Analyst: chris.witwer@nih.gov