

Can IRBs do anything about badly written consent forms?

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I've been on a hospital IRB for almost nine years. During that time I haven't seen much improvement in consent form writing styles. In a word, they're awful. Why can't multi-billion dollar drug companies and well-educated physician-researchers write consent forms that might get a passing grade in a high school English class? They should all be embarrassed to turn in this kind of writing.

I'm not talking just about readability. IRBs may "require" consent forms to be written at an eighth-grade reading level, but I doubt that many projects are disapproved if they don't meet that level. I suspect that IRBs seldom ask for grade-level measures (in writing) and rarely verify them independently. IRBs just don't have the personnel or time to be the readability police for every consent form they have to review. Plus, writers and IRBs will be deceived if they use the Flesch-Kincaid formula in Microsoft Word, which does not score higher than grade 12.

Do grade level recommendations = grade level research?

On the one hand, many IRBs set grade level standards for consent forms at usually about the eighth grade level. On the other, virtually every consent form readability study finds them to be written at grade levels much too high for average readers. Shouldn't these research findings be congruent with the recommendations?

Paasche-Orlow, Taylor & Brancan (2003), in their analysis of US medical school web site readability standards, found that an average number of medical schools recommend that consent forms be written at an eighth-grade level. But consent form templates posted on those web sites scored grade 10.6 on the Flesch-Kincaid and 13 on the Fry Readability Scale--a discrepancy of 2.8 to 5 grades between recommendations and examples. If consent forms must be written at an eighth-grade reading level why doesn't research on consent forms find that they're written at that eighth-grade level? That gap between recommendations and reality suggests that consent form writers do not (can not?) take readability requirements very seriously.

Readability or Writeability?

Readability software counts sentences, words, and syllables, but doesn't measure writing style. Consent forms written at an eighth-grade reading level can still be incomprehensible if they're written poorly. Since IRBs are required to have a non-scientific member, why not include a high school or junior high English teacher as a member with specific responsibilities for evaluating readability? Perhaps some blue-pencil comments by an English teacher would move IRBs beyond the minor cosmetic changes we usually suggest.

Edward B. Fry (1988), developer of the Fry Readability Scale, emphasized "writeability"--the writing, rewriting, or editing to get materials to a desired reading level. He noted that writers can cheat readability formulas by artificially cutting sentences in half (taking one long sentence and converting it into two or three short sentences), or by using short

words to replace long words. I've read too many consent forms that do exactly that--even though several short choppy sentences may be harder to understand than one longer sentence, and short words appear because the writer used the "find" and "replace" word processing function. Some consent form writers rely on a glossary to "translate" long words into short words; some have asked us if there is a software program that will do that automatically. They just don't understand reading or writing.

Are consent forms understandable?

But mechanical tinkering with words won't necessarily make consent forms any easier to understand. Consent forms are either written well or written poorly. Sometimes our IRB members can't understand important aspects of a project. If physician-researchers don't understand a consent form, how can scientifically naive human subjects be expected to understand it?

Human subjects must understand the research before they give "informed" consent. Otherwise, typical statements above the signature line such as "I have read and understand the preceding information..." or "I have read this consent form and understand the possible risks and benefits of my participation in this study..." are meaningless. Wouldn't it be interesting to have some extra space for subjects to list "the possible risks and benefits" they say they understand? Or following the typical, "I am not giving up any of my legal rights by signing this consent form," require subjects to list the legal rights they are not giving up. Demonstrated understanding means more than assumed understanding.

Improve consent forms by grading them?

Since grade level requirements haven't accomplished much, can anything be done to improve the written quality of consent forms? At the risk of antagonizing sponsors and researchers, IRBs should grade consent forms from "A" to "F," and only approve consent forms that earn at least a "C". Forms that get a "D" or "F" will have to be re-written, and won't be approved until they meet quality writing (not readability) standards. After a few revisions and delays, consent form writers should become proficient enough to routinely submit consent forms that at least meet minimal quality writing standards.

References:

Fry, E.B. (1988) Writeability: The Principles of Writing for Increased Comprehension. In Zakaluk, B.L. & Samuels, S.J., eds. *Readability: Its Past, Present, and Future*. Newark, DE: International Reading Association.

Paasche-Orlow, M.K., Taylor, H.A., & Brancan, F.L. (2003) Readability Standards for Informed Consent Forms as Compared with Actual Readability. *New England Journal of Medicine*, 348(8), 721-726.