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# Informed-consent documents called too long and complex

A study says clinical trial forms that run 20-plus pages are difficult to understand, and that medical liability fears may be prompting too many warnings.

**By KEVIN B. O'REILLY, amednews staff.** ***Posted Aug. 3, 2011.***

Despite years of guidelines urging simpler and easier-to-understand informed-consent documents, the forms given to clinical trial participants remain too long and use language that is too complex.

A review of 124 informed-consent documents used in 21 HIV clinical trials sponsored by the National Institutes of Health's Division of AIDS found that the forms were typically written above the ninth-grade level and ran longer than 22 pages. The findings were published online July 6 in the *Journal of General Internal Medicine* (**www.ncbi.nlm.nih.gov/pubmed/21748435/**).

"Very few people are going to sit down and read a document that's that long, and the goal is to have people understand," said Nancy Kass, ScD, lead author of the study. "The whole reason for putting [informed consent] in writing is with the belief that someone will read it. The longer it is, the less likely people are to read it all the way through, and then you have defeated your own purpose."

In 1998, the National Cancer Institute recommended that consent forms be written at an eighth-grade level. The institute also advised that forms be shortened, with further details provided through information sheets and explanatory videos. Most institutional review boards also recommend that consent forms be written at or below the eighth-grade level, as measured by the Flesch-Kincaid readability test.

Shorter, more readable forms are especially important when providing informed consent to participants with poor health literacy skills, said Kass, deputy director for public health at the Johns Hopkins Berman Institute of Bioethics in Baltimore.

Kass and her colleagues studied 21 "template" forms used in multisite trials, and they were typically shorter -- 16.8 pages long -- and more readable, scoring at the 8.7-grade level. But by the time 103 trial sites around the world were done making changes to these template forms, they ran nearly 24 pages and had a 9.4-grade level readability score.

## Legal concerns

Medical liability fears often drive trial sites to add more warnings to the forms, making them longer and more complex, said Kass, professor of bioethics and public health at the Johns Hopkins Bloomberg School of Public Health.

"That's the tension," Kass said. "All the liability fear seems to be related to not having been told something -- about a tiny, tiny chance that something bad would happen. ... The focus is on whether individual facts are being disclosed rather than creating an entire conversation that increases the chance of understanding."

Kass does see improvement. In the 1990s, most consent forms were written at the college-reading level.

"There was a tipping point with so much conversation about the Flesch-Kincaid level being so high that people writing consent forms really got it that they need to, and really can strive for, them to be less complex," Kass said. "We just need to have the same parallel narrative for length. These are smart people. They can solve this problem, too."



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