

Six Questions to Ask About Consent Form Readability

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If you're an IRB member or a researcher who submits projects to an IRB, you've probably dealt with consent form "readability." Although federal agencies and IRBs usually recommend that consent forms be written at a 6th–8th grade reading level—or even lower—there's no scientific justification for that recommendation. Here are six questions to ask regulators, research administrators, and IRB chairs about their consent form readability recommendations.

1) *What evidence concludes that consent forms should be written at a 6th–8th grade reading level?* I don't mean those articles with that unsupported recommendations, but evidence-based articles that have scientifically studied the link between grade level and informed consent comprehension. What data justifies that recommendation?

2) *Are consent forms at a 6th–8th grade reading level more comprehensible than those at higher grade levels?* There is very little quality research to support this conclusion. If a consent form is 24 single-spaced pages, will readability alone make a difference? See these skeptical reviews: Hochhauser, M. "Informed Consent. Reading and Understanding Are Not The Same." *Applied Clinical Trials*, 2004, 13(4), 42–44; 46; 48. Flory J. & Emanuel, E. Interventions to improve research participants' understanding in informed consent for research: a systematic review. *JAMA*, 2004, Oct 6;292(13):1593–601.

3) *Does it matter which readability formula you use? If so, why?* I analyzed a consent form that came to our IRB through Readability Suite (<http://www.oleandersolutions.com/>) which gives readability statistics for 17 formulas. The scores ranged from grade 11.5 to 16—a difference of 4½ grades. If the readability formula doesn't matter, use the lowest scoring formula. If you're using the Flesch–Kincaid formula in Microsoft Word be aware that older versions of Word do not report scores higher than grade 12.

4) *What does a 6th–8th grade reading level really mean?* Because most readability formulas were developed between 1948 (*Flesch Reading Ease*) and 1977 (*Fry Graph*), the statistical definition of 6th–8th grade 30–60 years ago may not be relevant in the 21st century. Flesch's Reading Ease formula, which is usually the standard to which other formulas are compared, estimated grade level based on 1940 US Census data (when average Americans had 8.5 years of education) and on 1925 student comprehension tests. Since the 2000 Census estimates average American have about 13.5 years of education, is Flesch's ancient readability data relevant to consent forms?

5) *What does it mean to write at a 6th–8th grade reading level? What about a 5th grade reading level?* This is purely a statistical definition. Based on Flesch's Reading Ease, 6th–8th grade means 14–17 words per sentence and 139–147 syllables per 100 words while 5th grade level means 11 words per sentence and 131 syllables per 100 words. This may be impossible to achieve.

6) *What are your liabilities?* Is your IRB potentially liable for recommending consent forms at a 6th-8th grade reading level but approving consent forms written at much higher grade levels? Could injured subjects sue because your IRB does not comply with its own recommendations?