

Topic: What Reading Levels Should Consent Forms be Written At?

Overview of the Topic

In regards to informed consent, the human subject regulations state that “The information that is given to the subject or the representative shall be in language understandable to the subject or the representative” (45CFR46.116; 21CFR50.20). This regulation refers to spoken or written languages such as Spanish, Arabic, etc., but also to the readability of the consent forms. Can subjects understand the words and concepts in the form? Or, is informed consent really being “informative?”

The average reading level of the US population is 8th grade. Of course that means that half of the population reads below an 8th grade level and half of the population reads above the 8th grade level. According to a study conducted by the US Department of Education and the National Institute of Literacy (August, 2016), 32 million adults in the US cannot read (14% of the population). Twenty-one percent of adults in the US read below a 5th grade level, and 19 percent of high school graduates cannot read. The literacy rate in the US has not changed for the last 10 years. These statistics highlight the challenges of trying to write a research consent form for the general population.

The problems in readability of research consent forms were illustrated in a study presented at PRIMR/AER in 2006 (Vasilenko and Burt) which used two different readability statistics to reveal that biomedical adult consent forms were written at a grade level of 12.7 or 13.9 while social science consent forms were at a grade level of 11.6 or 13.3. The average adult consent form was written four grade levels above recommendations. Many were written much higher.

One issue concerning readability is the use of scientific or medical terminology and acronyms. Consent forms attempt to explain often very complex research projects and it is difficult not to include related terminology. However, this terminology should also be explained in simple language to improve understanding. For example:

Field of Research	Acronym	Technical Definition	Simple Language Definition
Medicine/Cardiology	MI	Myocardial Infarction	Heart Attack
Medicine/Neurology	TIA	Transient Ischemic Attack	Blood flow to the brain stops for a short time
Psychology/Medicine	MMSE	Mini Mental Status Examination	Simple questions to show changes in mental functions
Sociology	NBDA	Network Based Diffusion Analysis	A way scientists use to look at relations among people and groups
Education	ASD	Autism Spectrum Disorder	Problems in children that can cause social, communication and behavioral concerns
Research Protection	IRB	Institutional Review Board	Committee that reviews research to help make sure it is safe and fair for participants.

Thus, a key to improve consent forms is to review forms closely for acronyms and jargon and either change them to more understandable wording or add simple definitions of complex terminology.

The other relevant issue in readability is the grade level that research consent forms are written at. When reviewing a consent form consideration should be given to who the population is that is being recruited as subjects. The eighth grade level is usually used for the general US population, for reasons explained above. For prisoners, a third grade reading level is advised. But if the subject population is limited to physicians, or physicians in a particular specialty, the reading level can be higher and acronyms and vernacular commonly used by physicians or specialists may be appropriately used. Child assent forms should be written at the grade level of the children. Hopefully investigators are considering their potential subject population and writing consent forms at the appropriate grade level, whether this be higher or lower than 8th grade. Unfortunately this is not usually the case, and thus IRBs need to help them.

Microsoft Word, the most commonly used word processing program, has built-in readability statistics. To turn on readability statistics in Word go to *Options, Proofing*, and check *Show Readability Statistics*. When you check spelling and grammar, reading statistics will be displayed after the spell check is complete. Word use the Flesch-Kincaid

readability program which uses the number of letters in words and the number of words in sentences to calculate a reading level. This is a very easy way to check the grade level of consent forms and then check again after revisions.

Here is an example of how the size of words can affect reading levels:

Now is the time for all good men to come to the aid of their party.

This sentence has 16 words and 52 characters and a Flesch-Kincaid Grade Level of 3.1.

Here is another version of the same sentence using larger words with the same meaning:

Currently is the chronological period when excellent males can come to the assistance of their acquaintances.

This sentence had 16 words, 94 characters and a Flesch-Kincaid Grade Level of 12.7.

You can see how bigger words increase reading level significantly. This is a good concept to convey to investigators and show them how to measure and utilize Word readability statistics to improve the readability of their consent forms. However, the IRB should also be aware that sometimes IRB required language can itself be problematic.

Consider the following examples which both have the same meaning:

Participation in this research protocol is voluntary. Reading grade level is 15.7

You do not have to be in this study if you do not want to. Reading grade level is 2.8

An issue is that we are highly educated people who read and write at a high level and are experts in our fields. We know and use the acronyms and vernacular of our field regularly, often without thinking. It is actually difficult for us to write at an eighth grade or below level, or even pick out language that might not be understood by an eighth grader. It may be beneficial for your IRB to recruit a member or consultant who has expertise in writing at reading levels of eighth grade or below. This is usually someone in education for writes for younger readers. Such a person can be useful to review and edit consent forms as well as educating the IRB on readability issues. They can also help revise any template consent forms used by your investigators to rewrite them at an appropriate level.

Most research consent forms are written at a level too high for the average population and impede understanding. But with attention paid to reading grade levels, acronyms and jargon, by both investigators and IRBs, consent forms can be crafted to be more readable, and fulfill the human protection obligations to provide “informed” consent.

By the way, this IRB EasyEd issue was written at a reading grade level of 10.7.

Questions for the IRB to Consider When Reviewing Readability of Consent Forms

1. What is the potential subject population and what should be the optimal reading level for that population?
2. What is the reading grade level of the consent form?
3. Are there acronyms or jargon which need to be replaced or simply defined?
4. Given questions 1-3, what changes will you require on the consent form?
5. What is the reading level of the revised consent form? Are the improvements acceptable?

Case Studies

Case 1. How would you handle the following acronyms in a consent form: MRI, CT Scan, CBC, ADHD, IRS, SSN?

Case 2. What reading grade levels do you think would be appropriate for the following populations: 1) Nurses
2) Medical Students and Residents 3) High school teachers 4) Pregnant teenagers 5) Veterans of recent wars
6) High School Seniors 7) Parolees from drug dealing offenses.

Case 3. A subject complaint is received by the IRB. The subject says that the consent form was poorly written and that she did not understand many of the words, procedures, and even what choices she had. The consent form in question was approved by the IRB and had been in use for a year. What should the IRB do to address the complaint?

Prospective Thinking: Conduct a reading level analysis of the last 10 consent forms approved by your IRB. Were they written at an acceptable grade level appropriate for the population? What changes in reading level, acronyms or jargon could have been done to improve readability. Experiment with the forms to see where and how you can make improvements. Check out an 8th grade text book or novel as examples of an 8th grade reading level.