

Suggestions on Improving the Readability of a Consent Form

Generally, CDC IRBs request that consent forms be written at approximately the 6th-8th grade reading level, and preferably closer to the 6th grade level. This is based on data of the reading level of the “average” American. However, if investigators believe that the reading level of the proposed study population is higher or lower, exceptions to this general rule will be considered by the IRB upon submission of an appropriate justification.

The guide, *Consent for CDC Research, A Reference for Developing Consent Forms and Oral Scripts*, was developed to assist investigators in writing consent forms that are easily understood by the majority of participants in CDC research activities. The *Guide* can be accessed through the CDC Office of Science Policy and Technology Transfer’s homepage at <http://www.cdc.gov/od/ads/consent.pdf> .

In addition to the document described above, below are some specific suggestions for reducing the reading levels of consent forms and improving comprehension of consent documents.

1. To assess the readability of the consent form using MSWord, do a Spelling and Grammar Check under Tools in the Menu. If there are no spelling or grammar errors detected, the readability statistics will be shown. The Flesch-Kincaid Grade Level is one measure of readability. If spelling or grammar errors are detected, simply “ignore” them to get to the readability statistics (under OPTIONS of the SPELLING AND GRAMMAR CHECKER), check the box marked “readability statistics,” and then continue.
2. If the first assessment of the consent form is at a level that is too high, try excluding the title and sponsor and investigator names if they occur as part of the heading or title of the document.
3. Institutional names or terms that are known to the study population, but which may be long/polysyllabic, can be simplified temporarily for determining readability. Use the Find and Replace function under Edit in MSWord, and replace the problematic terms with a simpler filler that can easily be replaced to restore the document to its original state. For example, replace “diabetes” with “sugar.” Then reassess the reading level.
4. To determine what parts of the document need more work to reduce the reading level, make sure that “show readability statistics” is checked under Tools, Spelling and Grammar, Options. Then highlight a section and run the Spelling and Grammar Check. Make sure that you answer the prompt asking if you wish to continue and check the rest of the document with a “no.” This will yield the Flesch-Kincaid Grade Level for the section. If you find that certain sections are at

a reasonable level, but others are not, you can then work at revising those at a high reading level.

5. The reading level can be lowered by reducing the number of long/polysyllabic words with simpler words, breaking long sentences into two or more separate sentences, and changing passive voice to active voice. Sentences with imbedding lists may be broken into a bulleted or numbered list. Tables can be used to simplify such information as study visits, procedures, time involved, and compensation.
6. Formatting a document into two-columns, although not affecting the Flesch-Kincaid Grade Level, does help to make it more readable. Newspapers and magazines adopted this format years ago. Material on the Internet (meant to be read off of the screen) also has narrow column widths to ease readability. These materials may also have printer-friendly versions to save paper when printing. Titles and the Consent Statement and Signature areas can still be kept full width. This reformatting is easily done using the Format, Columns function in MSWord.
7. Glossaries of simpler ways to describe medical terms are available to help in this process. These include:

<http://ovcr.ucdavis.edu/HumanSubjects/HSDefinitions/HSGlossary.htm>

Also, there are suggestions for replacement of words/phrases for polysyllabic terms that are common to CDC consent forms. They can be found on pages 59-60 of the guide *Consent for CDC Research, A Reference for Developing Consent Forms and Oral Scripts* at the following CDC intranet website:

<http://www.cdc.gov/od/ads/hsrconsent.pdf>

8. Headings written in upper and lower case are easier to read than those written in all caps. Headings can also be in a question format, asking the questions that the subject would ask and containing all the elements required for informed consent.
9. Often boilerplate language written by lawyers reads at a high reading level. Although CDC's Office of General Counsel is not involved with writing or approving consent forms for use in CDC-sponsored research activities, often our collaborators' institutions require mandatory boilerplate language that reads at a high level. If so, see if it can be simplified without losing its meaning. Ask the collaborators to check with their institution's IRB to see if the simplified language would be acceptable. If the language is still at a high reading level, but does not contain difficult to comprehend terms, you may still be able to use it if it does not raise the level of the entire document excessively. Often other parts of the document may be at a very low level and offset other parts that are at a higher level.

10. A simple check of the readability is to give the document to a 6-8th grade child and see if they can comprehend it.
11. For studies of higher risk, you may be asked to also incorporate a measure of comprehension into the protocol. This might be by piloting the document in individuals similar to those to be enrolled and asking a series of open-ended or multiple choice questions on key elements. Lack of comprehension in areas that need more explanation should become evident. Alternatively, some studies may require ensuring that each potential participant comprehends the key element. Assessment would then be done for each individual. Those that do not comprehend specific element would be reeducated. Those that did not comprehend after multiple attempts to educate would be denied participation in the study.
12. In some situations, for example, with illiterate subjects, oral consent is appropriate. Oral consent should be witnessed, and there should be some measure of comprehension of the process included. Please refer to 45 CFR 46.117(c) for additional information on waiver of documentation of informed consent.

To assess the reading level of a consent form for which there is no electronic version available, instructions for utilizing the “SMOG” formula are available at:

<http://www.cdc.gov/od/ads/smog.htm>

In addition, instructions for utilizing the Fry Graph Reading Level Index are available at:

<http://www.cdc.gov/od/ads/fry.htm>.