Suggestions on Improving the Readability of a Consent Form

Generally, CDC IRBs request that consent

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 term

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.