



Readability Guidance for Informed Consent Documents

According to the general requirements for informed consent under 45 CFR 46.116, "The information that is given to the subject or their representative shall be in language understandable to the subject or the representative."

The purpose of informed consent is to ensure that a potential research participant receives enough information to decide whether or not to participate in a research study. If a participant is unable to read and understand the consent document then they cannot properly consent to enroll into a research study. The Nova Southeastern University (NSU) Institutional Review Board (IRB) recommends that the reading level not exceed an 8th grade reading level when tested against the Flesch-Kincaid (FK) grade level readability test. Depending on the particular population involved in the study, the reading level may need to be increased or decreased. Some consent documents may be of such a technical nature that they may need to exceed the approximate 8th grade reading level. Investigators should discuss reading level concerns with their College Representative or IRB Office staff.

Writing tips to make your consent documents more reader friendly:

- Avoid medical terminology whenever possible. If a medical term must be used, define/explain it.
- Be consistent throughout the document with any words or terminology.
- Use numbers rather than words for numbers, e.g. "10" instead of "ten." However, if the first word of a sentence is a numeral, the word for the numeral is preferred.
- Restrict procedural descriptions to those the participant will experience and understand (i.e. tell them you will give a test or survey rather than naming the actual tool, or in clinical studies, that you are testing blood for a particular reason rather than naming the test).
- List procedures in chronological order.

Formatting tips to make consent documents more reader friendly:

- Make sentences short, simple and direct.
- Use short paragraphs and use lists rather than paragraphs when possible.

- Use headings/subtitles and **BOLD** them. These reduce content density and make it easier for participants to recognize consent document sections.
- Use an easy to read font and type size, making sure it is suitable for the participants involved. For example, 11 point Arial is the font the NSU IRB Office recommends and uses in our consent templates available on our website.
- AVOID USING ALL CAPITALS (hard to read). Only use capitals when grammatically necessary.
- Spell out abbreviated terms the first time you use them with the abbreviation in parentheses after the word(s), e.g., “Food & Drug Administration (FDA).
- Use the second person (you) rather than the third person (the patient/the subject) to increase personal identification.

How to get the Flesch-Kincaid (FK) Readability Score of a Document in Microsoft Word

1. Open Microsoft Word.
2. Click ‘File’ in the upper left hand corner.
3. Click ‘Options’.
4. Under Options, click ‘Proofing’
5. Under heading “When correcting spelling and grammar in Word’ select ‘Show readability statistics.
6. Click ‘OK’.
7. Run spellcheck on your document and at the end Word will present the Readability Statistics box. At the bottom of the box is the Flesch-Kincaid Grade Level Score.

As a general guideline researchers should use the following readability levels:

General Consent Form/Participant Letter Readability Level

Consent forms should be written at a readability level appropriate to the proposed participant population. For adults, it is recommended that consent forms not exceed the 8th grade reading level in most cases.

Child Assent Form Readability Level

For children ages 7-12, an assent form is used. The assent form should be written in a simpler format with language appropriate to the youngest child in this age range. It is recommended that the reading level be no more than 3rd or 4th grade. This form is required to be used with the Parent/Guardian Consent Form.

Adolescent Assent Readability Level

For children ages 13-17, the child signs the bottom of the Parent/Guardian Consent Form.

NOTE: Remember to take into account the reading level of your target participant population, the reading level may have to be lowered.