Readability Guidance for Informed Consent Documents

What is an informed consent form and why does readability matter?

Informed consent allows potential research participants to volunteer their participation freely, without threat or undue coercion. The potential participant is also provided with information an individual would want to know before participating, so an educated decision can be made whether or not to participate. This information must be provided in a way that can be understood by potential participants. If a participant is unable to read and understand the consent document, then they cannot properly consent to enroll into a research study. This is why IRBs talk about the "readability" (how easy or difficult it is to read something) of the informed consent. Readability depends on a text's presentation (such as font choice, spacing or colors) and context (the words and sentences on the page).

What are NSU standards for informed consent form readability?

The NSU IRB formatting standards are already included in our informed consent templates available on our website (https://www.nova.edu/irb/manual/forms/index.html). Consent forms should be written at a readability level appropriate to the intended participant population. The reading level of the final informed consent forms for adults should be no higher than an 8th to 9th grade reading level on the Flesch-Kincaid Grade Level scale, a common measurement of readability using grade level.

Researchers may need to decrease the reading level further depending on the population under study. The IRB also recognizes that formal names and definitions may skew readability. Researchers should discuss any needs for a higher reading level with their College Representative or the IRB Office prior to submitting their IRB submission.

For children or those with impaired decision-making capacity, their assent or consent forms must also be developmentally appropriate. For children ages 7-12, an assent form is used. The assent form should be written in a simpler format with language appropriate for the youngest child in this age range typically no more than 3rd or 4th grade.

How do I test the readability of my informed consent form?

To test the level and clarity of the consent form, we suggest that you:

1. Read the form out loud to colleagues or staff; AND
2. Use the word processing tool available to check grade level. The NSU IRB Office recommends using following website to get the Flesch-Kincaid Grade Level score https://readabilityformulas.com/free-readability-formula-tests.php

How can I improve the readability of my informed consent form?

1. Avoid use of acronyms or abbreviations. If you do use them, spell out acronyms when first used.
2. Use familiar words instead of technical jargon.
3. Avoid medical or other discipline-based terminology whenever possible. If a term must be used, define/explain it.
4. Be consistent with any words or terminology.
5. Use the second person (you) not third person (the participant) to increase personal identification.
6. Use active verbs.

7. Avoid contractions.
8. If possible, keep words to 3 syllables or fewer. For example, use the word *big* instead of *enormous*.
9. Be consistent with use of all terminology, such as drug names and abbreviations.
10. AVOID USING ALL CAPITALS (hard to read). Only use capitals when grammatically necessary.
11. Write short, simple, and direct sentences. Try to restrict sentence length to 20 words or less where possible.
12. When necessary, divide sentences into two. For example, break all compound sentences (and, but, because) into two short sentences.
13. Keep paragraphs short and limited to one idea. Five sentences per paragraph is a good goal.
14. Avoid large blocks of printed text. Use bullets, tables, or charts to make ideas clear.
15. List procedures in chronological order.
16. Restrict procedures to those the subject will experience and understand (i.e., tell them you will give survey rather than naming an unfamiliar instrument, or that you are testing blood for a particular reason rather than providing the technical name).

What are some examples of changes I can make to improve readability of my informed consent form?

- Instead of stating, "A survey will be administered online", you should state, "You will take a survey online."
- Instead of stating that "You must consume additional fluids while in this study in order to maintain hydration", you should state, "The study drug can make you thirsty. Drink plenty of water while you are in this study."

Where can I find additional help with readability?

NOTE: the following websites and word substitution links are helpful for drafting consent forms:

- Kids Health glossary of medical words – Provides layman descriptions of common medical terms that may be more easily understood by participants of all ages. (http://kidshealth.org/kid/word/)
- Stanford glossary of lay terms –Translates commonly used scientific and research terms into lay language that may be more easily understood by participants. (https://researchcompliance.stanford.edu/panels/hs/for-researchers/definitions)
- Word Analyzer—Provides information about a given word, such audience familiarity, to show how using a word may affect readability scores. The analyzer then shows synonyms and related words your audience may be more familiar with. (https://datayze.com/word-analyzer)
- Hemingway Editor - Assists with grammar and word choices in your writing. (https://hemingwayapp.com/)
- Federal Plain Language Guidelines - General tips on how to make communication simple and clear. (https://plainlanguage.gov/media/FederalPLGuidelines.pdf)

**** This document is written at a 7.9 reading level on the Flesch-Kincaid Grade Level scale. ****