

Improving Consent Form Readability & Comprehension

Why is readability and comprehension important?

The Belmont Report (sets out basic ethical principles governing research involving human subjects) makes the following points about informed consent:

- "The reasonable volunteer" standard: the extent and nature of information should be such that persons, knowing that the procedure is neither necessary for their care nor perhaps fully understood, can decide whether they wish to participate in the furthering of knowledge. Even when some direct benefit to them is anticipated, the subjects should understand clearly the range of risk and the voluntary nature of participation.
- The manner and context in which information is conveyed is as important as the information itself.
- Because the subject's ability to understand is a function of intelligence, rationality, maturity and language, it is necessary to adapt the presentation of the information to the subject's capacities.

What is the purpose of the consent form template?

- It contains the required elements of consent per federal regulation
- Supports reading level standards
- Supports readability and comprehension strategies
- Includes appropriate space for document versioning and the IRB stamp
- Contains language that has been vetted as acceptable by the compliance and legal departments
- Provides consistency across the university
- Decreases the likelihood of required modifications to the consent form

What types of readability & comprehension strategies are available?

- Reading level
 - Strive to write consent forms and parent permission forms at a 6th to 8th grade reading level. Assent forms for minors should be written to the child's grade level but no higher than an 8th grade level.
 - Since federal regulations require information provided to a potential subject to be in a language understandable to that subject, a lower reading level of an English language form could prevent a researcher from having to obtain a written translation for non-native English speakers that have more than limited working proficiency but less than native or bilingual proficiency in English.
 - Use readability tools in your word processor or other software to help calculate an estimate of the reading level.
- Formatting
 - Use adequate spacing and white space to make the content inviting to read. Avoid crowding of words and letters.
 - Use headings/subtitles. These reduce content density and serve as "road signs."
 - Use lists rather than paragraphs when possible.
 - A one page consent form is not a goal!

Improving Consent Form Readability & Comprehension

- Words/Sentences/Paragraphs
 - Use words with 1-2 syllables rather than longer words. Prefer common, familiar words to less common, less familiar words. Keep a Thesaurus handy.
 - Examples: administer = give; determine = find out; in conjunction with = at the same time; participate = take part.
 - Spell out abbreviated terms the first time you use them with the abbreviation in parentheses after the word(s).
 - Use short sentences (no more than 20 words per sentence)
 - Use short paragraphs (no more than 10 lines per paragraph)
 - Use numerals instead of words for numbers, such as “10” instead of “ten” or “1 out of 2” instead of “one out of two.” However, if the first word of a sentence is a numeral, the word form should be used.
- Print Size & Type
 - Use large print size (12 point or larger)
 - Use clean, easy to read print type.
 - Paper: Serif fonts are easier to read on materials that will be printed out and read on paper. Examples include: Times New Roman, Palatino, Georgia, Courier, Bookman and Garamond.
 - Online/Email: Sans-serif fonts are easier to read online and in email. Examples include: Helvetica, Arial, Calibri, Century Gothic and Verdana.
 - Avoid using all capitals since it is harder to read.
 - Avoid use of **bold type** which can lead to subjects overlooking information not in bold type.
- Person/voice
 - Use 2nd person (you) rather than 1st person (I) or 3rd person (the subject/he/she).
 - Use active voice instead of passive. Write the way that you would talk.
- Type of Information
 - Focus on priority, “need to know” information. Omit non-essential information such as complex theoretical, scientific, or medical background
 - Avoid research or academic “lingo.” If lingo must be used, define each term.
 - Avoid complex scientific or medical terminology.