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Investigator Guidance:
How to Prepare a Readable Consent Form

The UM Institutional Review Boards (IRB) ask that research teams make every effort to ensure that informed consent documents be written at an approximate 8th grade level when tested against the Flesch-Kincaid (FK) grade level readability test. The IRB recommends the use of this tool as it is available as a feature within Microsoft Word's Spelling and Grammar check. The IRB recognizes that some consent forms are of such a technical nature that it may not be possible to keep to an approximate 8th grade reading level. The investigator may discuss problems she/he has in trying to keep consent text at a low reading level with the staff at the HSRO.

The purpose of informed consent is to ensure that a prospective research participant receives enough information to decide whether to participate in a research study. This will not happen if the participant is not able to read and understand the document. Readability plays a role here. Many consent forms are written at about the 10th grade level, which is above the reading level of 50 percent of the US population.

There are many required elements in the informed consent form, and we understand researchers often find it difficult to reduce the reading level. The best solution is to start from the beginning to design and write the consent form using the language and format that makes it easy for your audience to understand what your project is about and what you are asking them to do.

Readability formulas examine word length and sentence length. This does not really equate to what children or youth can read and understand. Readability formulas are only a way to present the level of reading ease for the document. There is no perfect reading formula. Some other readability formulas available include the Simple Measure of Goobledygook (SMOG) or the Fry Readability Formula.

Simple Words

- Avoid medical terminology whenever possible. If a medical term must be used, define/explain it.

Avoid	Prefer
anorexia	lack of appetite
edema	swelling
insomnia	trouble sleeping
intradermal	under the skin
malignancy	cancer
postoperative	after surgery
subcutaneous	under the skin
venipuncture	draw blood

- Avoid research lingo such as “arms of a trial.” For research lingo that must be used, define each term. For example, “randomize (as if by tossing a coin, or as if in a lottery);” “placebo (an inactive substance such as a sugar pill).”
- Use words with 1-2 syllables rather than longer words. Prefer common, familiar words to less common, less familiar words. For example:

Avoid	Prefer
administer	give
anticipate	expect
commence	begin, start
determine	find out, see if
difficulties	problems
discontinue	stop
evaluate	assess
experience	have
indicate	show
induce	cause
investigation	study
in conjunction with	at the same time as
manifest	appear
minimize	lower, reduce
participate	be in, take part
require	need
terminate	stop
utilize	use

- Avoid empty phrases.

Avoid	Prefer
Despite the fact that	Although
For the purpose of	For
On account of the fact that	Because
Was of the opinion that	Believed
With the exception of	except

- 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.

Describing Study Procedures

- Consent forms for projects that involve collection of blood or other fluids should include the amount(s) to be taken. Do not use ‘ml.’ or ‘cc.’ as a volume measure; give a volume equivalent in teaspoons or tablespoons. Rather than abbreviating such words as teaspoon and tablespoon, please spell them out.
- Do not use the words “treatment” or “therapy” to describe an investigational drug, device or procedure. Use the term "study drug," not "study medication" when the drug is investigational. The word "medication" or "medicine" should only be used if the drug is commercially available for that particular condition.

- Do not describe investigational drugs, devices or procedures as “new.” For investigational drugs or devices, state they are investigational or “experimental” and describe that term (e.g., the word "investigational" means the study drug is not approved by the U. S. Food and Drug Administration (FDA) and is still being tested in research studies.) Be consistent in using “investigational” throughout the consent form.
- Use "study doctor" instead of “principal investigator" and "research study" instead of "trial."
- Use the word "participant" in the consent form instead of “patient” since this is research. However, you may use “patient” when referring to the person prior to his/her entering the study.
- Do not use the word “invite” (for example, “You are invited to participate in a research study.”). Instead use, “You are being asked to participate in a research study because...”
- For optional portions of the study (e.g., asking permission to store samples for future research), insert lines for initials or checkboxes to allow a subject to indicate his/her choice.

Formatting

- Use adequate spacing and white space to make 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.
- Use short sentences (no more than 20 words/sentence).
- Use short paragraphs (no more than 10 lines/paragraph).
- Use large print size, preferably a serif font (serifs are the bars on the tops and bottoms of letters). This guidance is written in 12 point, Times New Roman font.
- AVOID USING ALL CAPITALS (hard to read). Only use capitals when grammatically indicated.
- Avoid use of **bold type,** which can lead a reader to overlooking information not in bold type.
- Use the second person (you) rather than the third person (the patient/the subject) to increase personal identification.
- 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).
- Brand names of drugs or devices must be capitalized and include either the trademark or registered symbol the first time the drug name is mentioned.
- Generic drug or device names are lowercase.

Enabling Readability Statistics in Microsoft Word

1. Click the **File** tab, and then click **Options**.
2. Click **Proofing**.
3. Under **When correcting spelling and grammar** in Word, make sure the **Check grammar with spelling** box is selected.
4. Select **Show readability statistics**.
5. Click **OK**.

After you enable this feature, open a file that you want to check, and check the spelling. When Word finishes checking the spelling and grammar, it displays information about the reading level of the document.

NOTE: This document is written at a 9th grade level.