The UNE Office of Research Integrity recommends that Participant Information Sheets (for exempt research projects) and Consent Forms (for non-exempt research projects) meet the **Flesch-Kincaid Grade Level 8** (or below) readability standards. Documents that do not meet this criterion *may be returned* for revisions to improve participant understanding depending on the proposed target population to be recruited.

For questions related to this guidance, please reach out to the Office of Research Integrity at irb@une.edu.

Background

The average reading level among U.S. adults is no higher than the eighth grade. Among economically or educationally disadvantaged populations, the average reading level is even lower, about the fifth grade. Many research participants do not understand consent forms because these documents are typically written at the college or graduate school level.

The Principal Investigator is responsible for ensuring that research participants have an adequate understanding of the procedures, risks, and benefits before they participate in the study. Researchers should strive to write Participant Information Sheets or Consent Forms at a sixth to eighth grade level unless prospective participants are known to read at a much higher or lower reading level.

Writing Participant Information Sheets or Consent Forms with a low level of reading difficulty is a skill that can be learned. The information below includes tips and strategies to reduce reading levels within these documents.

Flesch-Kincaid Grade Level

The Flesch-Kincaid Grade Level is a widely used readability formula that assesses the approximate reading grade level of a text, based on average sentence length and word complexity. It produces scores corresponding to U.S. grade levels. For example, if a text has a Flesch-Kincaid level of 8, this means the reader needs a grade 8 level of reading or above to understand it.

Instructions for how to calculate the Flesch-Kincaid grade level of a document are provided below.

For PC users: For Microsoft Word, (1) on the "File" tab, click the "Options" button; (2) on the "Proofing" tab, under "When correcting spelling and grammar in Word", make sure "Check grammar with spelling" is selected; (3) under "When correcting spelling and grammar in Word", select the "Show readability statistics" check box. After the grammar check is complete, Word displays a message box showing you the readability grade level].

For Mac users: For Microsoft Word, select Word > Preferences on the browser toolbar. Choose Spelling & Grammar. Under Grammar, select Check grammar with spelling and Show readability statistics. In your Word document, select Review > Spelling & Grammar. Correct or ignore any spelling or grammar corrections, then click "Editor" under the Home toolbar and "Document stats" under "Insights." Word will open the Readability Statistics window with information about the reading level of your document.

Tips for Drafting a Readable Participant Information Sheet or Consent Form

- ❒ Use words familiar to the non-medical reader.
- ❒ If possible, keep words to 3 syllables or fewer.

- ❒ Write short, simple, and direct sentences. Divide sentences into two when necessary.
- ❒ Keep paragraphs short and limited to one idea.
- ❒ Use active verbs.
- ❒ Use the second person (you) not third person (the participant) to increase personal identification.
- ❒ Avoid contractions.
- ❒ Use page numbers on all participant-facing documents.
- ❒ Use at least 12-point font and consider a larger font based on your audience.
- ❒ Check the text to see if each idea is clear and logically sequential.
- ❒ Highlight important points; use underlines, bold, and boxes rather than italics or all caps.
- ❒ Avoid repetition.
- ❒ Avoid large blocks of printed text.
- ❒ Use photos, graphics, or tables if they will help clarify procedures.
- ❒ Be consistent with the use of all terminology, such as drug names and abbreviations.
- ❒ 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.
- ❒ Use the appropriate abbreviation the first time a drug name is used in the consent.
- ❒ Abbreviations such as DNA, HIV, and AIDS that have come to be accepted as standard by your proposed study population need not be spelled out.
- ❒ Do not use e.g., etc., use instead, "for example," "so forth."
- ❒ Spell out acronyms when first used.
- ❒ In general, do not use capital letters (all CAPS), or bold items.

Tips for Describing Study Procedures in a Biomedical Research Consent Form

- ❒ Consent forms for projects that involve the 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. Please spell them out rather than abbreviating such words as teaspoon and tablespoon.
- ❒ Do not use symbols such as ">"; use "greater than."
- ❒ Describe study design procedures such as "double-blind," "randomized," and "placebo/controlled" when the concept(s) is/are first introduced. Example: "A placebo is an inactive substance that looks like the study drug, but contains no medication."

- ❒ 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 use the term "treatment” or “therapy” if one of the study arms will be a placebo. Instead, use words like: “study product”, “study drug or placebo,” “study regimen” or “study procedure”
- ❒ Do not describe investigational devices, or procedures as “new.” For investigational devices, state they are investigational or “experimental” and describe that term (e.g., the word "investigational" means the study device 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" (more understandable to a layperson) instead of “principal investigator."
- ❒ Use "research study," instead of "trial."
- ❒ Use the word "participant" instead of “patient” since this is research. However, you may use “patient” when referring to the person prior to them 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 (insert condition here).”
- ❒ When describing randomization for 2 groups use, “like the flip of a coin,” for more than 2 groups, use "like drawing numbers from a hat."
- ❒ 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 their choice.

Additional Resources

a) Glossary of Medical Words: (http://kidshealth.org/kid/word/)
b) Clinical Research Glossary: (http://www.firstclinical.com/icfglossary/)
c) Glossary of Lay Terms: (Medical Terms in Lay Language for use in Consent Forms)
d) Plain Language Resources for Research: (PRISM Readability Toolkit)