Institutional Review Board

Institutional Review Board Guidelines and Policies Guidelines

II. Informed Consent Guidance - How to Prepare a Readable Consent Form

April 2016

The JHM IRB recommends that the reading level of the informed consent document should be no higher than an 8th grade level. The IRB recognizes that some consent forms are of such a technical nature that it may not be possible to keep to an 8th grade reading level. The investigator may discuss with the OHSR Consent Form Specialists problems she/he has in trying to keep consent text at a low reading level.

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

a) read the form out loud to colleagues/staff and test it on a target audience; and

b) use the word processing tool available to check grade level.

[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]

Drafting tips for preparing consent forms:

- 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 protocol, consent and any other 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 underline, bold, 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 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. or 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

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 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 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" (more understandable to a lay person) instead of “principal investigator."
- Use "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 (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."
- If the FDA may approve the study drug while the research study is in process, include information on whether participants will be responsible for paying for the study drug if it is approved.
- 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.
- For double-blind studies, include a statement that the blind can be broken in case of an emergency. Example: “In the case of an emergency, the study doctor can quickly find out to what study group you are assigned.”

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

a) Glossary of medical words: (http://kidshealth.org/kid/word/)

b) Clinical Research Glossary: (http://www.firstclinical.com/icfglossary/)

c) Glossary of lay terms:
(http://humansubjects.stanford.edu/general/glossary.html)