Use of Language and Readability of the Informed Consent Document

Readability of Informed Consent

Basic Principles of Readability:

- Write at 8th grade level or below
- Use common, everyday words
- Define complex words using "Alternative word suggestions" or Glossary of Human Subject Terminology in lay language
- Use short sentences < 15 words
- Use active form
- Use formatting (Bullets, white spaces, shaded boxes) to improve the visual understanding. Use visual aids, examples, analogs

Appropriate Use of Language

The IRB should ensure that technical and scientific terms are adequately explained, and that complex scientific concepts are properly converted into simple concepts that the typical subject can read and comprehend. Although not prohibited by the FDA regulations, use of the wording, "I understand..." in informed consent documents may be inappropriate as many prospective subjects may not fully "understand" the scientific and medical significance of all the statements. Consent documents are more understandable if they are written just as the clinical investigator would give an oral explanation to the subject, that is, the subject is addressed as "you" and the clinical investigator as "I/we." This writing style also helps to communicate that there is a choice to be made by the prospective subject. Use of first person may be interpreted as presumption of subject consent, i.e., the subject has no choice. Also, the tone of the first person "I understand" seems to misplace emphasis on legal statements rather than on explanatory wording enhancing the subject's comprehension.

Subjects are not in a position to judge whether the information provided is complete. Subjects may certify that they understand the statements in the consent document and are satisfied with the explanation provided by the consent process (e.g., "I understand the statements in this informed consent document"). They should not be required to certify completeness of disclosure (e.g., "This study has been fully explained to me," or, "I fully understand the study.")

The FDA discourages use of phrases such as, "FDA has given permission..." or "FDA has approved..." in consent documents. Technically, the FDA does not "approve" drug studies under an IND (Investigational New Drug) Application. FDA does approve device studies under IDE (Investigational Device Exemption).

Consent documents should not contain unproven claims of effectiveness or certainty of benefit, either explicit or implicit, that may unduly influence potential subjects. Overly optimistic representations are misleading and violate FDA regulations concerning the promotion of investigational drugs [21 CFR 312.7] or investigational devices [21 CFR 812.7(d)] as well as the requirement to minimize the possibility of coercion or undue influence [21 CFR 50.20].

The FDA believes that an explicit statement that an IRB has approved solicitation of subjects to participate in research could mislead or unduly induce subjects. Subjects might think that, because the IRB had approved the research, there is no need to evaluate the study for themselves to determine whether or not they should participate.

The informed consent documents may not contain any exculpatory language through which the participant is made to waive or appear to waive any of the participant’s legal rights, or releases or appears to release the investigator, the sponsor, the University, or its agents from liability for negligence.

Non-English Speaking Subjects

In the case of a non-English speaking subject, the FDA fully expects that a translated version of the ICF will be provided to the study subject. IRB approves the translated ICF prior to utilization.

A person who reads and speaks this language should administer the consent; alternatively, a translator could be called in, however, while a translator may be helpful in facilitating conversation with a non-English speaking subject, routine ad hoc translation of the consent document should not be substituted for a written translation.

If a non-English speaking subject is unexpectedly encountered, and investigators do not have a written translation of the consent document and the IRB has approved the research for inclusion of non-English speaking subjects, the investigators must rely on oral translation. Investigators should carefully consider the ethical/legal ramifications of enrolling subjects when a language barrier exists. If the subject does not clearly understand the information presented, the subject's consent will not truly be informed and may not be legally effective.
If investigators enroll subjects without an IRB approved written translation, a "short form" written consent document, in a language the subject understands, should be used to document that the elements of informed consent required by 21 CFR 50.25 were presented orally. The UC Davis IRB has a list of pre-approved short forms available for this use. Documentation of a short form is described in 21 CFR 50.27(b)(2). Briefly, when a short form consent document is to be used the IRB should review and approve the written summary of the full information to be presented orally to the subjects. An impartial witness is required to attest to the adequacy of the consent process and to the subject's voluntary consent. Therefore, the witness must be present during the entire consent interview, not just for signing the documents. The subject or the subject's legally authorized representative must sign and date the short form and a copy of the summary. The witness must sign and date both the short form and a copy of the summary, and the person actually obtaining the consent must sign and date the short form and a copy of the summary. The subject or the representative must be given a copy of the signed and dated summary as well as a copy of the signed and dated short form.

The translator should be fluent both in English and the language understood by the subject/representative. The translator may be a family member or friend of the subject/representative. The translator can also act as the impartial witness.

Impartial witness is a person not involved in the design, conduct, or reporting of the research study. The impartial witness may be a family member or friend.

**Illiterate English-Speaking Subjects**

A person who speaks and understands English, but does not read and write, can be enrolled in a study by "making their mark" on the consent document, when consistent with applicable state law. In addition, if a subject is unable to read or if a legally authorized representative is unable to read, an impartial witness must be present during the entire informed consent discussion. After the written informed consent form and any other written information to be provided to subjects, is read and explained to the subject or the subject’s legally authorized representative, and after the subject or the subject’s legally authorized representative has orally consented to the subject’s participation in the trial and, if capable of doing so, has signed and personally dated the informed consent form, the witness should sign and personally date the consent form. By signing the consent form, the witness attests that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject or the subject's legally authorized representative, and that informed consent was freely given by the subject or the subject’s legally authorized representative.

Impartial witness is a person not involved in the design, conduct, or reporting of the research study. The impartial witness may be a family member or friend.

**Physical disabilities preventing reading or writing**

A person who can understand and comprehend spoken English, but is physically unable to talk or write, can be entered into a study if they are competent and able to indicate approval or disapproval by other means. The subjects may be entered into the study if:

1. the person retains the ability to understand the concepts of the study and evaluate the risk and benefit of being in the study when it is explained verbally (still competent), and

2. is able to indicate approval or disapproval to study entry.

The consent form should document the method used for communication with such subject and the specific means by which the subject communicated agreement to participate in the study. Consent should include a statement indicating the reason for the subject’s inability to sign the document and a statement that an impartial witness was present during the process.

An impartial third party should witness the entire consent process and sign the consent document. A video tape recording of the consent interview is recommended.

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