Obtaining and Documenting Informed Consent of Subjects Who Do Not Speak or Read English

Modified: January 2017

Background:

Federal Regulations require that information given to a subject as part of the consent process be in language understandable to the subject. Documentation of informed consent by use of an IRB-approved written consent signed by the subject or the subject’s legally authorized representative (LAR) is required unless the IRB has determined that the criteria for waiver of written informed consent is met.

Q: What are the requirements for obtaining and documenting informed consent of subjects who do not speak or read English?

Research investigators may seek informed consent only under circumstances that provide the prospective subject sufficient opportunity to consider whether or not to participate in a research study and that minimize the possibility of coercion or undue influence. Informed consent information must be presented in a language understandable to the potential subject and should embody all the necessary elements for legally effective informed consent.

If the research population under study is primarily non-English speaking, the IRB-approved informed consent should be translated into the native language of the subject population, and a back-translation of the document, performed by a qualified third party, should be submitted for IRB review following approval of the final version of the English consent document.

Q: Is a translated consent required for studies where the population under study is primarily English-speaking?

No. An alternative may include a short form written consent in a language understandable to the subject stating that the elements of informed consent required by the Federal Regulations have been presented orally to the subject or the subject's LAR. When this method is used, there must be a witness to the oral presentation who is fluent in both English and the language of the subject. The IRB-approved English-language consent can serve as the written summary of what is to be said to the subject or the LAR. All English and Non-English consent forms, including the short form, and recruitment materials must be reviewed and approved by the IRB prior to their use.

Q: What is the process for obtaining and documenting informed consent using the IRB approved short form?

1. A competent interpreter fluent in both English and the subject’s native language should present an oral translation of the written summary of the study in a language understandable to the subject.

2. The IRB-approved English version of the informed consent may serve as the written summary.
3. A member of the research team who is approved by the IRB to obtain informed consent (as indicated in the IRB approved Submission) must be present to participate in the process to seek and obtain consent.

4. A witness, fluent in both English and the subject’s native language, must be present for the informed consent discussion. The competent interpreter may serve as the witness.

5. After all questions are answered and the subject verbalizes understanding and willingness to participate:
   a. The subject (or LAR) should sign and date the short form consent.
   b. The witness should sign and date both the short form consent and the written summary (IRB-approved English version of the informed consent).
   c. The person obtaining consent should sign and date the English language version of the IRB-approved informed consent.

6. The subject (or LAR) should receive copies of the short form consent and the written summary (typically the IRB approved informed consent for the study).