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

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.

1. 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 must be translated into the native language of the subject population, and a back-translation of the document. Translations and back translations must be performed by a qualified third party, must be submitted for IRB review following approval of the final version of the English consent document.

2. 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.

3. Q: If you are primarily seeking consent from subjects who do speak and read English, but unexpectedly want to enroll someone who does not speak or read English, what is required?

Federal regulations allow the use of a “short form” translated into the subject’s native language.” The IRB approved “short form” is available on the IRB website written in Spanish or Hindi. The “short form” is a generic consent form that states general requirements required under the regulations such as the subject is being asked to participate in research; they can refuse to participate without penalty, contact information for the IRB, etc. Based on an analysis of the population in Gainesville, the IRB has already approved short forms in Spanish and Hindi.
In addition to the use of the “short form”, the study staff must include the following when consenting a non-English speaking study subject:

- **Interpreter**: Have a competent interpreter fluent in English and the subject’s native language.
- **Summary**: The competent interpreter should present an IRB approved written summary of the protocol. The IRB approved Informed Consent form written in English can serve as the written summary.
- **Researcher**: A member of the research team who is approved by the IRB to obtain informed consent should participate in the process, answer questions, and seek informed consent.
- **Witness**: A witness who is fluent in English and the subject’s native language must witness the informed consent discussion. The competent interpreter may serve as the witness.
  - If the subject gives consent to participate, the following must occur:

The subject (or LAR) must sign and date the “short form”; in additions:

- The witness should sign and date (a) the “short form” and (b) the IRB approved Informed Consent written in English
- The person obtaining consent should sign and date the IRB approved Informed Consent written in English
- Give the subject copies of the “short form” and the IRB approved Informed Consent written in English.

We advise that you make a research note to file to document that the above process occurred.

4. **Q: What if you need a “short form” for a subject who speaks a language other than Spanish or Hindi?**
   - You will need to have the “short form” translated by a qualified third party. This should include a back-translation to English to verify the translation is appropriate.
   - Obtain IRB approval: the IRB must review and approve this translated document. Submit a minor revision to your study. If this is the only change you make the IRB should be able to quickly review and approve the revision.