Non-English Speaking Subjects and Short-Form Consent

Subjects who do not speak English should be presented with an IRB-approved informed consent form written in a language understandable to them. The IRB must review and approve all foreign language versions of informed consent forms. Documentation must be provided that a certified translator performed the translation.

Using a short-form consent form

An alternative to using an IRB-approved translated consent form is the short form consent form. A short form consent document is a brief document, written in the subject's preferred language. The study investigator should ensure that communication with the subject will be effective during the recruitment process, consenting, and duration of the study. The short form consent document should attest that HHS and FDA required elements have been presented orally to the subject or legally-authorized representative. The IRB should review the summary of the elements presented.

The short form consent document must contain the following:

- A description of the required elements of informed consent;
- An explanation that the purpose of the research, the study procedures and the other required elements in the consent form will be presented to the subject, or legally authorized representative in their preferred language; and
- A statement that the key information was presented first to the subject, before other information, if any, was provided.

Before beginning the consent process, the investigator should determine if the interpreter will serve as the witness, or if another person is needed to fulfill that role. The witness should be conversant in both English and the language of the participant. To consent a non-English-speaking subject using the short form, the following should be done during the consent process:

- Present the study elements orally in the subject's language
- Have a witness to the presentation who is conversant in both English and the subject's language (someone other than the person doing the presentation)
- Have the subject (or subject's legally-authorized representative) and the witness sign the short form
- Have the witness and the person obtaining consent sign the summary; the IRB-approved English language informed consent document may serve as the summary
- Provide a copy of the summary and the short form to the subject or legally-authorized representative

The witness can be the interpreter/translator, a member of the study staff, a family member, or another person. The interpreter should be a hospital interpreter.

Signatures:
The witness will sign both the short form and a copy of the summary

The person obtaining consent will sign a copy of the summary
The subject (or legally-authorized representative) will sign the short form

A sample short form consent form can be found at:

https://www.hhs.gov/ohrp/regulations-and-policy/guidance/obtaining-and-documenting-infomed-consent-non-english-speakers/index.html#sample