FRED HUTCH
Institutional Review Board

SHORT FORM PROCESS TIP SHEET

For Consenting Non-English Speakers

To use the short form process, the IRB must first have approved:

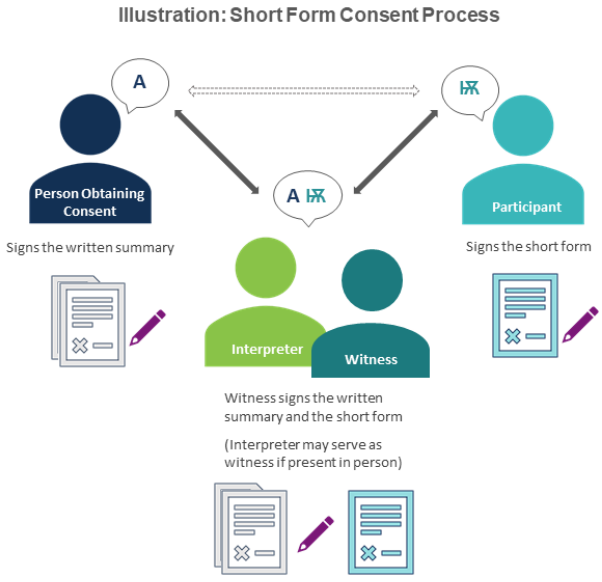
1. enrollment of non-English speakers in this study
2. use of the Short Form Process for enrolling non-English speakers into this study
3. a waiver of the HIPAA signature (unless there is a pre-translated HIPAA form in target language)

Documents needed:

- ❑ IRB-approved English consent form
- ❑ Translated short form (available from IRO's website)
- ❑ HIPAA authorization (if applicable to the research) – translated if available

People present:

- ❑ Participant (and/or participant's LAR)
- ❑ Person obtaining consent
- ❑ Interpreter (may serve as witness only if in person)
- ❑ Witness (may be a family member if they speak English and the target language)



Signatures:

Consent:

- Participant or LAR signs the short form and HIPAA)
- Witness signs the short form **and** the English consent form
- Person obtaining consent signs the Engl. consent form

HIPAA:

- If translated form: Participant signs.
- If using English version: No one signs the HIPAA, but researcher documents that a verbal authorization was obtained.

Interpreters Serving as a Witness

As an in-person interpreter for a research consent discussion, you are also asked to serve as a "witness." Federal guidance allows for an interpreter to serve as the witness during the short form consent process.

In addition to interpreting the consent discussion, you will be asked to sign the short form and the consent form indicating you served as the witness. **This does not in any way mean you are being held legally responsible for the consent process. It means you witnessed the oral presentation and the participant's apparent willingness to take part.**

Background

Federal regulations allow for a "short form" consent process to be used with non-native English speakers.

In this process, the informed consent information is presented orally, via an interpreter, in conjunction with a translated short form consent document and a "written summary" of what is presented orally (the English consent form).

A witness to the oral presentation is required, and that witness must be fluent in both English and the participant's language.

A family member who speaks both languages may not serve as the interpreter but may serve as the witness.

A telephone interpreter is acceptable for this process, but in that case the interpreter may not serve as the witness. A family member or caregiver accompanying the patient may serve as the witness if they speak both English and the target language.

Citations

See Fred Hutch IRB webpage for additional details about involving non-English speakers/readers in research: https://extranet.fredhutch.org/en/u/irb/informed-consent/non-english-speaking-participants.html

45 CFR 46.117(b)(2)

HHS Guidance: Informed Consent of Subjects Who Do Not Speak English (1995), available at https://www.hhs.gov/ohrp/regulations-and-policy/guidance/obtaining-and-documenting-infomed-consent-non-english-speakers/index.html

FDA Guidance: A Guide to Informed Consent (1998), available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guide-informed-consent