Fred Hutch Cancer Center

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 all of the following:

1. Enrollment of non-English speakers on this study
2. Use of the short form consent process for enrolling this population
3. If applicable, a waiver of the HIPAA signature (unless there is a pre-translated HIPAA form in target language)

Documents needed for consent discussion:

- ❑ IRB-approved English consent form
- ❑ Translated "short form" consent in the individuals' preferred language (IRO's website)
- ❑ If applicable, HIPAA authorization in English or translated

People present for entire discussion:

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

Signatures:

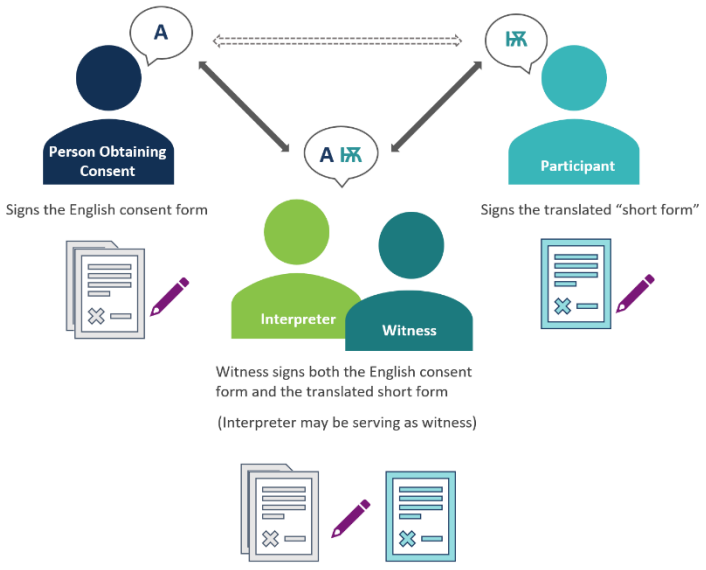
Consent:

- Participant or LAR signs the short form
- Witness signs the short form **and** the English consent form
- Person obtaining consent signs the English consent form

HIPAA:

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

Illustration: Short Form Consent Process



If the participant consents to join the study via the short form process:

1. The English version of the consent form must be translated and submitted to the IRB within 30 days of the consent conference.
2. After IRB approval, the translated consent form must be provided to the participant as soon as possible and within 2 weeks. (The translated form may be provided to the participant via MyChart, email, mail, or at the next clinic visit. It does not need to be signed, and a re-consent discussion is not required.)

For 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-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 the English 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.

NOTE: "Non-English speakers" should be understood to include (1) individuals who do not speak English at all, (2) those with some English but at a low level of proficiency that would not allow them to participate in meaningful informed consent, and (3) those with another language preference.

References

See Fred Hutch IRB webpage for additional details about involving non-English speakers/readers in research: https://centernet.fredhutch.org/cn/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: Informed Consent (2023), available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/informed-consent