

Consent Process Examples

Consent Process for Non-English Speaking Participant

Description: Informed consent information must be presented “in a language understandable to the participant,” and in most situations the consent must be documented in writing (45 CFR 46.116 and 46.117). If the participant speaks or reads English, but is only comfortable conversing in an official manner in their primary language, the primary language should be used to obtain consent. The IRB strongly encourages the use of a fully translated consent document in the participant’s primary language. However, there may be circumstances where this is not feasible; in such cases, a short form consent process may be used.

A short form consent process provides a translated summary of the research (called a short form) to the non-English speaking individual, along with the English consent document. A person qualified to provide language interpretation or converse with the participant in their primary language is used to describe all elements in the English consent that are not described in the short form. An independent witness must observe the short form consent process and sign the documentation.

Because of the need to converse with the individual in a language other than English, additional provision for conducting and documenting the consent process are needed. This example illustrates the steps a study team might take to obtain consent from a person who does not speak English as their primary language.

The IRB must first approve a consent process that outlines this procedure. The details of the procedure to obtain consent must be provided on the Consent Process page of the New Study Application in ERICA.

- 1. Provide the participant with all the required information about the study in a language the participant understands.** Give a copy of the consent document(s) to the participant, either on paper or electronically.

When using the Short Form Consent Document & Process: Provide the translated short form in the participant’s primary language as well as the full consent document in English.

When using the Fully Translated Consent Document & Process: Provide the fully translated consent document.

Secure language services for conducting the consent process conversations, either a qualified interpreter or a qualified member of the study team, as allowable under IRB policies. When using the Short Form Consent Document & Process, ensure you

have an independent witness to the consent process, which can also be the qualified interpreter.

Use of interpretation services may be accommodated in person or via remote methods such as telephone or video call.

2. **Give the participant an opportunity to ask questions before providing consent.** Inform the individual that if they would like to take more time to consider the study, a follow-up conversation can be scheduled.
3. **Document that the participant's consent was obtained before beginning study procedures.**
 - a. Ask the individual if they would like to participate. If yes, obtain the following signatures:

When using the Short Form Consent Document & Process:

- i. Participant signs the translated short form in their primary language.
- ii. Witness signs the translated short form and the full English consent document.

Notes:

- i. *When the qualified interpreter is acting as a witness, the Interpreter Statement in the signature block is used to document the witness signature.*
- ii. *When the witness is participating remotely (via telephone or video call), a verbal attestation can be documented instead of a signature. Read the witness signature statement aloud to the witness and document their verbal or written attestation in the consent process note to file.*
- iii. Person obtaining consent signs the full English consent document.

The "Participant Signature Block" portion of the English Consent Document is not signed by the participant when a short form process is used.

When using the Fully Translated Consent Document & Process:

- i. Participant signs the fully translated consent document in their primary language.
- ii. Person obtaining consent signs the fully translated consent form.

4. Write a note to file that documents the interaction:
 - i. When the consent form was given to the participant
 - ii. When the consent conversation occurred
 - iii. What was discussed during the consent conversation
 - iv. Who provided language services for the consent conversation

- v. *If using an interpreter:* Interpreter information, including name, affiliation, and qualifications
- vi. *If the short form was used:*
 - i. Who served as the independent witness to the consent process
 - ii. *If the witness participated remotely:* note that the witness signature statement was read aloud to the witness and verbal or written attestation was given
- vii. When a copy of the fully signed document(s) was given to the participant

5. **Give a copy of the signed consent document(s) to the participant.** This can be provided either on paper or electronically.