

Short Form Consent Process for Non-English Speakers

Participants who have limited or no English proficiency may be enrolled in your research provided that you have the resources to communicate effectively with the participants during the recruitment process, while obtaining consent, and for the duration of the study. The inclusion of non-English speaking participants must be approved by COMIRB. If you anticipate enrolling non-English speakers, address the recruitment, consent, and conduct of study visits with non-English speaking participants in your IRB application.

A short form consent may be used when a potential participant does not speak English and there is not enough time to translate the English version of the approved consent document into a language the potential participant understands. A short form consent document attests that the elements of informed consent, as required by DHHS and the FDA, have been presented orally to either the participant or the participant's legally authorized representative (LAR).

COMIRB has translated Short Forms on our website. If you do not find a short form in the language you need, contact COMIRB. We can usually provide a certified translation within three business days. If a translation is needed sooner than this, you will have to get the English short form translated into the appropriate language.

A short form may be used up to three times in the same language. If a fourth participant is to be enrolled, the entire consent form must be translated. The translated consent form must be submitted to COMIRB for approval. Attach a copy of the translator's credentials or a certification of the translation. After the translated consent form is approved, any previous participants still on study should be re-consented with the translated consent form as deemed appropriate.

HIPAA

When requesting COMIRB approval for a short form consent process, you will need to download a copy of the English version of the stand-alone HIPAA Authorization, complete it as necessary for the specific study, and include it with the other study documents for COMIRB approval.

When you wish to obtain short form consent from a non-English speaking participant, download the appropriate translations of the short form and the stand-alone HIPAA authorization. Add study information to the top of the short form. Edit the HIPAA Authorization to match the approved English version for your study.

Short Form Consent Signatures:

- **English version of the consent form is signed by the person obtaining consent and the witness**
- **Translated short form is signed by the participant and the witness**
- **Translated stand-alone HIPAA Authorization is signed by the participant**

The witness:

- **Serves as witness to the oral presentation**
- **Need not be fluent in the language**
- **Must be impartial and independent of the study team**
- **May be a family member of the participant**
- **May be the interpreter if present in person**

The Short Form Consent and HIPAA Authorization Process

Enrolling a non-English speaking participant with a Short Form generally involves four parties:

1. The participant
2. The person obtaining consent
3. An interpreter (might not be needed if the person obtaining consent is fluent in the language)
4. A witness to the oral presentation

The approved English version of the consent form is used by the person obtaining consent and the interpreter to obtain consent and to make sure all the elements of informed consent have been presented orally to the participant or participant's legally authorized representative (LAR).

Signatures

If the participant agrees to be in the study:

1. The English version of the consent form is signed by the person obtaining consent and the witness.
2. The short form is signed by the participant and the witness.
3. The stand-alone HIPAA Authorization is signed by the participant.

The Witness

The role of the witness in this situation is to verify that the oral consent process took place in the participant's (or LAR's) language. The witness need not be fluent in the language to verify that an appropriate interpreter was involved. The witness must be impartial and independent of the study team, and may include a family member of the subject or a hospital staff member who is not part of the study team. Also, if the interpreter is present in person, the interpreter may serve as the witness. If the interpreter is involved remotely (*e.g.*, by video conference) a separate witness should be used.

Reportable Events

If your protocol is not approved for the enrollment of non-English speaking participants and there is insufficient time to obtain such approval prior to enrolling a participant, and there is appropriate justification for using the short form without approval, you must submit an Unanticipated Problem form to report the use of the short form without COMIRB approval. Additionally, you should submit a concurrent amendment to request approval for any future enrollment of non-English speaking participants.

Research Records

A statement in the research records (and on the English consent form) should indicate that the participant did not speak English and identify the interpreter.

Hospital Policies

Each of our affiliate health systems has policies regarding the involvement of non-English speaking patients. Researchers need to be sure they conduct their study in compliance with health system policies.