

Research Compliance Office

Short Form Consent Process

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Non-English speaking participants



Investigators are encouraged to recruit and include all segments of our community in research, including individuals whose primary language is not English.

Participants who do not speak English should be presented with a consent document written in a language understandable to them.





- The Stanford HRPP and OHRP encourage the use of a full consent form translated into the participant's language whenever possible
- However, **with prior approval of the IRB**, federal regulations **permit the use of a short form** consent process (45 CFR 46.117(b)(2) and 21 CFR 50.27(b)(2))

What to submit for IRB Approval



Intention to use the short form consent process - add in the "consent" section of the protocol application.

Note: If the Stanford-provided translated short form documents are used it is not necessary to submit the actual form for IRB approval.

(Stanford approved: Chinese, Farsi, Koren, Russian, Spanish, and Vietnamese)

What to submit for IRB Approval



Summary Form (Modified English consent form):

Modified to have a signature line and text added on the last page beneath the Person Obtaining Consent section, as follows:

The following witness line is to be signed only if the consent is provided as a summary form and accompanied by a short form foreign language consent.

Signature

(e.g., staff, translator/interpreter, family member, etc.)

Date

Protocol Application



Consent Background - Windows Internet Explorer

Consent Background Save

Short Form Consent Process

Consent Information Type: *

Title: *

- Download the [short form consent](#) in required language and add to the header: Study Title, Protocol Director, and Contact Information. If the participant speaks a language other than one available on our website, you must submit a short form version in that language to the IRB for approval before enrolling the participant.
- Add lines to the full English consent form for Witness Signature and Date.
- If the Person Obtaining Consent does not speak the participant's language, you must use a translator/interpreter. A family member may act as the translator/interpreter if the participant has declined the services of a hospital translator/interpreter.
- A witness, who is bi-lingual in English and the participant's language, must be present during the entire consent process. The translator/interpreter can act as the witness. After the study is described to the participant by the translator/interpreter, the participant and witness must sign the short form consent and the Person Obtaining Consent and the witness must sign the full English consent.

I have read and will follow the above procedures.

Consent Form (file name): Browse...

Save

Translators/interpreters and witnesses who are they and what do they do?



- The assistance of a **translator/interpreter** and the presence of a **witness** are **required for the short form consent process.**

- Who can be the translator/interpreter?
 - Preferably, a hospital translator/interpreter
 - A family member of the participant (only if the participant has declined the use of a hospital translator/interpreter)
 - Study staff, if they speak the participant's language

Translators/interpreters and witnesses who are they and what do they do?



Who can be the witness?

- There must be a witness to the oral presentation who speaks both English and the participant's language.
- The witness may be staff, the translator/interpreter, a family member, or other person.

Translators/interpreters and witnesses who are they and what do they do



- **Before starting the consent process:**
 - Verify whether the translator/interpreter will also be able to serve as a witness - if not, you will need to obtain another person to act as the witness.
- **A member of the study staff acting as translator/interpreter and Person Obtaining Consent should **not also act as witness.****

During the consent process



- **The translator/interpreter should briefly explain the consent process to the participant.**
- **The short form document in the participant's language should be given to the participant to read.**
- **The translator/interpreter should translate the English consent to the participant.**
- **A copy of the signed and dated short form should be given to the participant or their legally authorized representative.**
- **A copy of the Summary Form (the modified English consent form) should be given to the participant or their LAR.**

Signature Requirements



- If the participant agrees to take part in the study, the following signatures are required:

- ***Short Form (in persons language) must be signed and dated by:***
 - i) Participant, or the participant's legally authorized representative [LAR]
 - ii) Witness

- ***Summary Form (English) must be signed and dated by:***
 - i) Person obtaining consent
 - ii) Witness



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