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Investigators are strongly encouraged to recruit and include all segments of our community in research, including individuals whose primary language is not English. Participants who do not understand 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 the 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)).

The IRB determines if use of the short form consent process is appropriate and can be approved. The IRB may require that a participant be re-consented using a fully translated consent in the participant's language within 30-days of enrollment for certain studies (e.g., first-in-human, high risk).

If a non-English speaking participant is initially consented through an approved short form process, to the extent that the study involves high risk, first-in-humans, or ongoing interventions or interactions over an extended period of time, the IRB may require re-consent using a fully translated consent form in the participant's language within 30 days of enrollment.

A description of the process used to obtain the short form consent should be provided in the "consent background" of the protocol application. The IRB expects the investigator to have an understanding of the short form process as follows:

- If the Person Obtaining Consent (POC) is not fluent in the participant's language, an interpreter must be present to assist in the consent process.
 - The interpreter must be fluent in English and the language of the participant. A family member may be the interpreter only if the participant has declined use of a hospital interpreter.
 - If the participant agrees to take part in the study, the following signatures are required:
 - Short Form (translated):
 - i) Participant, or the participant's legally authorized representative [LAR]
 - ii) Witness*
 - Summary Form (English):
 - i) Person Obtaining Consent (POC)
 - ii) Witness*
- * The witness may be the interpreter (including the hospital interpreter), study staff, a family member.
A member of the study staff acting as interpreter *and* POC *cannot* also act as witness.
- The participant should be given a copy of both the translated Short Form and the Summary Form.

Note:

- The non-English speaking participant/LAR *does not* sign the English consent.
- If the participant or the LAR is non-English speaking, the POC must ensure:
 - the LAR's Description of Authority is completed, and

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- o any questions or options presented by the consent form are documented and initialed by the POC on the Summary Form, per the participant's wishes, as they are understood during the consent process.

The IRB provides many Short Form template translations on the [Human Subjects Website](#).

Federal Regulations for Short Form Consent Process and Documentation

OHRP: 45 CFR 46.117(b):

(b) Except as provided in paragraph (c) of this section, the consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by §46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

(2) A short form written consent document stating that the elements of informed consent required by §46.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.**FDA: 21 CFR 50.27(b):**

(b) Except as provided in 56.109(c), the consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by 50.25. This form may be read to the subject or the subject's legally authorized representative, but, in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed.

(2) A *short form* written consent document stating that the elements of informed consent required by 50.25 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining the consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative in addition to a copy of the short form.