

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.

If a non-English speaking participant is initially consented for a study through an approved short form process, to the extent the study includes ongoing interventions or interactions with the participant, investigators will assess the feasibility of translating the full English consent into the participant's language whenever possible.

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 is not fluent in the participant's language, a translator/interpreter must be present to assist in the consent process. The translator/interpreter must be fluent in English and the language of the participant. A family member may be the translator/interpreter only if the participant has declined use of a hospital translator/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
- ii) Witness*

The participant should be given a copy of both the translated Short Form and the Summary Form.

The IRB provides Short Form templates on the [Human Subjects Website](#) in: Chinese, Farsi, Japanese, Korean, Russian, Spanish and Vietnamese.

*The translator/interpreter may serve as the witness.

[See reverse for Federal Regulations for Short Form Consent Process and Documentation]

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.

[See reverse for guidance for Short Form Consent Process]