Consent Translated into Participant's Language
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 when a non-English speaking participant is unexpectantly encountered (45 CFR 46.117(b)(2) and 21 CFR 50.27(b)(2)).

Short Form Process
The IRB determines if use of the short form consent process is appropriate and can be approved. The IRB requires that a fully translated consent in the participant's or legally authorized representative's (LAR) language be provided to the participant or LAR promptly after the short form is used for certain studies involving investigational biologics, drugs, and/or devices.

A description of the process used to obtain the short form consent should be provided in the "consent background" of the protocol application and the English consent form should include the Person Obtaining Consent (POC) and Witness signature lines. The investigator must agree to follow the procedures specified in the protocol application for use of the short form consent process. The IRB expects the investigator to understand the short form process as follows:

- If the POC is not fluent in the participant's language, an interpreter must be present to assist in the consent process.
- Before starting the consent process, verify whether the interpreter will also be able to serve as a witness; if not, another person must act as a witness.
- The POC must ensure that any questions or options presented in 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.

Interpreters and Witnesses
The short form consent process requires the assistance of an interpreter (who speaks the participant's language and English fluently) and the presence of a witness.

- Who can be the interpreter?
  - Preferably, a qualified hospital interpreter in any modality whenever possible.
  - In certain situations, such as an emergency or when the participant has declined the use of a qualified interpreter, a family member of the participant may act as an interpreter.
  - If a member of the study staff speaks the participant's language, the staff member can act as the interpreter and POC.
- Who can be the witness?
  - A person who attests to the oral presentation.
  - The witness may or may not be the interpreter.
  - Study staff acting as POC cannot also act as witness.

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

- Short Form (translated):
  - Participant, or the participant's legally authorized representative [LAR]
  - Witness

- Summary Form (Modified*English Consent Form):
  - Person Obtaining Consent (POC)
  - Witness

Additionally, the participant does not sign the English consent form. The participant should be given a signed and dated copy of both the translated Short Form and the Summary Form.

*Modified to have a signature line and text added on the last page beneath POC section, see Informed Consent Template.

HIPAA
If protected health information under the HIPAA Privacy Rule is involved, request an Alteration of HIPAA Authorization in the application (or Waiver of HIPAA Authorization for VA studies). The alteration means that when using the Short Form Consent Process, neither the participant nor their LAR should sign the HIPAA Authorization (whether there is a separate HIPAA Authorization or one embedded in the Summary Form.

Short Form Templates
The IRB provides many Short Form template translations on the Human Subjects Research Website. If the Stanford-provided translated short form documents are used, it is not necessary to submit them for IRB approval. A certification of translation for these templates is available on the website. If a participant speaks a language other than what is templates are online, the English version of these forms is available on the website for use in translating into the target language.

These templates include the basic required elements of informed consent and the Experimental Subject's Bill of Rights (California Law). These documents do not contain study specific information, but state what will be explained to the participant about the specific study by the interpreter (e.g. key information, purpose of the research, expected duration, procedures, risks, benefits, alternatives [if any], confidentiality of information, compensation [if any] for research-related injuries, whom to contact for questions about the research and research subjects' rights, that participation is voluntary, future use of the participants' information or biological specimens, and whether information about the research will be submitted for inclusion in a clinical trial registry).

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 informed consent form 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, and that the key information required by §46.116(a)(5)(i) was presented first to the subject, before other information, if any, was provided The IRB shall approve a written summary of what is to be said to the subject of the legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Only the short form itself is to be signed

by the subject or the subject's legally authorized 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 subject's legally authorized 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.