UCSF Office of Ethics and Compliance
Human Research Protection Program

Quick Guide: Consenting Non-English Speaking Participants
Please review the HRPP website for complete guidance.

Two Methods for Obtaining Consent from Non-English Speaking Participants

If you anticipate that your study may enroll non-English speaking participants, explain in the IRB Application which method(s) of consent you will utilize. **IMPORTANT: The IRB must approve the enrollment of non-English speakers before they can be enrolled.**

1. *Preferred Method* – The researcher obtains written translations of the IRB-approved consent form(s) *after the study is approved.* The researcher submits translated consent materials to the IRB as an administrative modification before enrolling participants with the translated consent form(s) and translated consent addendums as approved study changes require re-consent.

2. *Short-form Method* – This method only should be used for the **occasional and unexpected enrollment** of a non- English-speaking subject in a study for which there is no translated consent form in the subject's language. Instead of signing the English-language consent form (which the subject does not understand), the subject is presented with and asked to sign the Experimental Subject's Bill of Rights in his/her native language. **Routine use of this method is strongly discouraged by the University and Federal Regulators. If a study enrolls more than 2 participants that speak the same non-English language, the consent form should be fully translated.** The Short Form method can be used to facilitate re-consent for changes affecting the approved Informed Consent document.

For both methods:

- Use a qualified interpreter to present the consent form info to the potential subject and facilitate the consent discussion.
- By answering and asking questions, the person obtaining consent determines whether the subject comprehends the consent information to ensure the informed consent is valid.

Preferred Method Documentation		
Translated Informed Consent (IRB Approved)	**Experimental Participant's Bill of Rights** (Download in the subject's language – contact IRB for add'l translations)	**HIPAA Authorization**
Signatures required: 1. Participant 2. Person obtaining consent Document in the research file that an interpreter was used. Give a signed copy to the participant.	**Signatures required**: None Give a copy to the participant.	If you need to obtain HIPAA authorization from the participant, follow the instructions on page 3.

Short Form Method Documentation		
English-Language Informed Consent (IRB Approved)	**Experimental Participant's Bill of Rights** (Download in the participant's language – contact IRB for add'l translations)	**HIPAA Authorization**
Signatures required: 1. Person obtaining consent 2. Witness Document in the research file that an interpreter was used. Give a signed copy to the participant.	**Signatures required (see "Important Notes"):** 1. Participant 2. Witness Write a statement on the Bill of Rights that the elements of consent were presented orally. Give a signed copy to the participant.	If you need to obtain HIPAA authorization from the participant, follow the instructions on page 3.

Hint: The participant and person obtaining consent sign the document that they each understand – that is, the participant signs the Bill of Rights in his/her native language and the person obtaining consent signs the English consent form.

Important Notes

- ***Who can sign as a witness using the short form method?*** The witness is signing to document that an oral presentation in a language the participant can understand took place. The witness can be the interpreter or another adult (other than the person obtaining consent) who witnesses the involvement of an interpreter. Preferably, this adult would not be a family member of the participant, unless the person is a health professional or otherwise knowledgeable about research.

- ***Short form signature lines*** – If necessary, add the required signature and date lines by hand to the form. Each signature line should have its own date. In addition, write or type a statement on the Bill of Rights that the elements of consent from the consent form were presented orally.

- ***Who is a "qualified interpreter"?*** – Although it may be necessary in *very rare* cases to have a bilingual family member serve as a medical interpreter, this practice is strongly discouraged. The medical and technical information discussed during the consent process and throughout the study can be very complex and should be communicated through an interpreter with training and understanding in medical terminology**.**

- As such, medical interpreters *or* investigators (or perhaps knowledgeable Key Personnel) who are fluent in English and the language in question should conduct the consent form translation. In the latter case, the investigators and Key Personnel should ensure that they are truly capable interpreters and can translate the complex medical terminology adequately.

- ***Translating the consent form*** – The interpreter does not need to "read" an entire consent document to the potential participant. As in a normal consent process, the person obtaining consent should ask the interpreter to provide the participant with key information about the study (e.g. the elements of informed consent described on the Bill of Rights).

Obtaining HIPAA Authorization (UCSF Subject Authorization for Release of PHI for Research)

If you need to obtain HIPAA authorization* from a non-English-speaking participant, follow the instructions based on whether a translated UCSF HIPAA Authorization form is available in the participant's language.

1) ***A translated UCSF HIPAA Authorization form* is *available in the participant's language:*** The participant should sign the translated form. An interpreter does not need to sign the translated form. However, an interpreter should be available to speak with the participant about this form, and document in the research file that an interpreter was available.

2) ***A translated UCSF HIPAA Authorization form* is *NOT available in the participant's language:*** Please facilitate translation of the HIPAA Authorization Form into the participant's native language before facilitating the consent process.

*Note: The SF VAMC Authorization for Release of PHI for Research is only available in English. It must be signed by the participant, interpreter and the person obtaining the authorization. Check with other institutions about their HIPAA requirements.