UCSF Office of Ethics and Compliance
Human Research Protection Program

Quick Guide: Consenting Non-English Speaking Subjects

Please review the HRPP website for complete guidance.

Two Methods for Obtaining Consent from Non-English Speaking Subjects

If you anticipate that your study may enroll non-English speaking subjects, 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 subjects with the translated consent form(s).

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.

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

Short Form Method Documentation

English-Language Informed Consent (IRB Approved)	**Experimental Subject's Bill of Rights** (Download in the subject'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 subject.	**Signatures required (see "Important Notes"):** 1. Subject 2. Witness Write a statement on the Bill of Rights that the elements of consent were presented orally. Give a signed copy to the subject.	If you need to obtain HIPAA authorization from the subject, follow the instructions on page 2.

Hint: The subject and person obtaining consent sign the document that they each understand – that is, the subject 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 subject 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 subject. As in a normal consent process, the person obtaining consent should ask the interpreter to provide the subject 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 subject, follow the instructions based on whether a translated UCSF HIPAA Authorization form is available in the subject's language. The form currently is available in 19 languages.

1) ***A translated UCSF HIPAA Authorization form* is *available in the subject's language:*** The subject 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 subject 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 subject's language:*** Verbally translate the English-language UCSF HIPAA Authorization form. The subject, the interpreter, *and* a separate witness must sign the form. The witness can be a member of the research team.

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