Consenting Non-English Speakers

See the Quick Guide on Consenting Non-English Speakers [1] for a summary of this info.

Background

The San Francisco Bay Area is a diverse region [2], and you likely will encounter eligible subjects with limited English proficiency when recruiting locally. The governing principles of human subject research [3] require that investigators a) not exclude subjects based solely on their inability to read, speak or understand English and b) find a way to communicate with

subjects to ensure that consent is voluntary and informed.

Federal regulations from OHRP [4] and FDA [5] state that informed consent ?shall be in language understandable to the subject or the representative? and describe how consent is to be documented. California state law also requires the Experimental Subject's Bill of Rights [6] be provided ?in a language in which the subject is fluent? to individuals participating in a biomedical study.

Two Methods of Consent: Preferred and Short Form

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.

Preferred Method: The preferred method is to provide consent forms written in the subject?s language. The researcher obtains and submits written translations of the IRB-approved consent form(s) after the study is approved.

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 signs a "short form consent" ? the Experimental Subject?s Bill of Rights [6] in his/her language. **Routine use of this method is strongly discouraged by the University and federal regulators.**

Reminders for Both Methods

The IRB must approve the enrollment of non-English speakers in your study.

You must indicate in the IRB Application that non-English speakers will be enrolled, and the IRB must approve this request **before** you can enroll non-English speakers.

Describe the consent process for non-English-speaking subjects in the IRB Application.

Clarify who will be conducing the consent process and how this person will communicate with non-English speakers.

Use a**qualified interpreter** (not a family member) to facilitate the consent discussion.

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 Study Personnel) who are fluent in English and the language in question should conduct the consent discussion. In the latter case, the investigators and Key Study Personnel should ensure that they are truly capable interpreters and can translate the complex medical terminology adequately.

By answering and asking questions through the interpreter, the investigator determines whether the subject comprehends the consent information to ensure the informed consent is valid.

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. More information on interpreters is available below.

Explain how you will continue to communicate with non-English speakers throughout the study.

Informed consent is an ongoing process throughout the study, so describe how you will provide continued, qualified interpretive services throughout the study.

It is the investigator?s responsibility to judge the subject?s comprehension of the consent info.

It is the investigator?s responsibility to evaluate the subject?s comprehension of the consent information, including the understanding that participation is voluntary and that the subject has the right to withdraw at any time during the study. If the investigator doubts the subject?s consent comprehension, do not enroll the subject in the study. **The subject?s safety must not be endangered due to a language barrier.**

Allow sufficient time for explaining each section of the consent and for the subject to ask questions. Working with an interpreter to explain complex topics such as randomization, placebo control, dosing schedules and invasive/noninvasive procedures may require additional time and/or subsequent discussions.

Contact the IRB if the Experimental Subject's Bill of Rights is not available in the subject's language.

The IRB will obtain a translation of the document for you at no cost to you. Please contact us [7] in advance of the consent visit to allow time for us to obtain the translation.

Preferred Method

The IRB strongly encourages you to use the preferred method and provide subjects with a written consent document in language they can understand. In particular, use the preferred method if you anticipate a substantial portion of eligible subjects will be non-English-speakers.

A qualified interpreter should facilitate the consent process. If you are conducting a biomedical study, provide the subject with a copy of the Experimental Subject?s Bill of Rights [6] in a language in which the subject is fluent. If HIPAA applies to your study, review information on obtaining HIPAA authorization.

IRB Review Process for Translated Consent Materials (Preferred Method)

Step 1. PI requests approval to enroll non-English speakers and submits English-language consent and other study documents

- In the "Subjects" section of the IRB Application, indicate that you wish to enroll non-English speakers. Then describe in the IRB Application the consent process for non-English speakers and identify languages likely to be encountered in the subsequent section.
- Attach the English-language consent documents only. Also submit English-language versions of recruitment materials or other study materials that will need to be translated.

Step 2. The IRB reviews and approves this request

- If needed, the IRB requests changes to the English-language consent materials and PI submits the revised versions.
- IRB approves the consent plan and consent documents.

Step 3. PI obtains translations and submits them as an administrative modification

- Researcher obtains accurate written translations of the IRB-approved English consent documents.
- Researcher submits translated consent documents and other study materials that required translation to the IRB before enrolling subjects using the translated language consent form. Submit these materials in iRIS as an administrative modification [8].

Preferred Method Documentation

Translated Informed Consent (IRB Approved)	**Experimental Subject?s Bill of Rights[6]** (Download in the subject's language ? contact the IRB [7] 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. Only required for biomedical studies [6] when using the preferred method.	If you need to obtain HIPAA authorization from the subject, follow the instructions below.

Short Form Method

The ?short form? method for obtaining informed consent should only 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. **The University and federal regulators strongly discourage routine use of the short form method.**

Short Form Consent Method Steps:

Step 1. PI requests IRB approval to enroll non-English speakers using the short form consent method

In the "Subjects" section of the IRB Application, indicate that you may wish to enroll the occasional and unexpected non-English speaker. Then describe how you will conduct the short form consent process for non-English speakers. The IRB must approve the use of the short form [9] in your study before you utilize this method.

Step 2. A qualified interpreter helps present the consent info and facilitates the consent discussion

A qualified interpreter assists in orally presenting the IRB-approved informed consent information to the subject. By answering and asking questions, the investigator determines whether the subject comprehends the consent information to ensure the informed consent is valid.

Step 3. The subject signs the short form consent doc, the Bill of Rights in the subject's language

In addition to the oral presentation, the subject must sign a short form written consent document. The Experimental Subject?s Bill of Rights [6] translated into a language in which the subject is fluent will serve as the short form. A witness also must sign.

Short Form Method Documentation

English-Language Informed Consent (IRB Approved)	**Experimental Subject?s Bill of Rights[6]** (Download in the subject's language ? contact the IRB [7] 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.	The Bill of Rights written in a language in which the subject is fluent serves as the ?short form.? **Signatures required:** 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 below.

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.

Short Form Method FAQs

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 witnessed 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.

How do I add the short form signature lines to the Experimental Subject's Bill of Rights?

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 [6] that the elements of consent from the consent form were presented orally.

Does the interpreter need to translate the consent form verbatim?

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

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 [10] is available in the subject?s language.

A translated UCSF HIPAA Authorization form is available in the subject?s language

The subject should sign the translated form [10]. 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.

A translated UCSF HIPAA Authorization form is NOT available in the subject?s language

Verbally translate the English-language UCSF HIPAA Authorization form [11]. The subject, the interpreter and a separate witness must sign the form. The witness can be a member of the research team.

The subject is being enrolled at the SF VAMC

The SFVAMC Authorization for Release of PHI for Research [12] 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.

Providing a Qualified Medical Interpreter

The medical and technical information discussed during the initial consent discussion and throughout the study can be very complex. It should be communicated to non-English speaking-subjects through an interpreter with training and understanding in medical terminology, as well as a professional commitment to maintain strict confidentiality.

Although it may be necessary in some rare cases to have a bilingual family member or staff person serve as a medical interpreter, keep in mind the following issues.

- The routine use of ad hoc interpreters should be avoided.
- Children should not be asked to serve as an interpreter.
- Complex ideas and treatment regimens may demand that a trained professional be employed.
- Issues of privacy must be considered if family members are asked to translate.

Contacting In-Hospital Medical Interpreter Services

UCSF Medical Center

During regular business hours, call the Ambulatory Care Services at 415-353-2690. After

hours or on the weekends, call Nursing Administration at 415-353-1797.

San Francisco General Hospital

During business hours, call 415-206-5133. After business hours, call 415-206-8000.

Working Effectively with Medical Interpreters

Topics to discuss with interpreters

The field of medical interpretation is evolving, so here are some topics you may want to discuss with the interpreter before participating in an interpreter-assisted consent discussion.

- How transparent will the interpreted conversation be? With three people communicating (subject, investigator and interpreter), will everything said by each person be translated?
- Informed consent is an ongoing process. How will the investigator ensure that the subject will understand ongoing study-related communication? If the subject has questions about continuing in the study, how will that be communicated to the researchers?
- If the English version is presented orally for the alternative ?short form? method, how will the interpreter incorporate cultural considerations into the consent information?

Professional organizations

- The American Translators Association [13], including a Directory of Translation and Interpreting Services [14]
- The California Healthcare Interpreter Association (CHIA) [15]
- The National Council on Interpreting in Health Care (NCIHC) [16] provides a guide for assessing medical interpreters.

Translating Study Documents

After the IRB reviews and approves the consent documents and other study materials (such as advertisements or questionnaires), the investigator is responsible for having these documents translated.

The investigator is responsible for the cost of translating study materials. These costs may be quite high. Include the costs of written translations, as well as medical interpreter services, on grants and contracts. Industry sponsors often are willing to pay these costs.

Translation companies (Note: The IRB does not endorse any translation service.)

- The Language Bank [17]
- TransPerfect [18] ? email UCSF@transperfect.com [19] for assistance
- Northwest Translations Inc [20]
- Real World Solutions (RWS) Group [21]
- Accredited Language Services (ALS) [22]

Validating translations

Although not required by the IRB, here are some means of validating translations:

- A ?certified translation? includes a notarized statement by the translator that he/she understands English and the target language and may list the translator?s credentials. A copy of the certification should be attached to the translation.
- A professional translator ?back translates? the consent into English to verify equivalent meaning in the target language.

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Links
[1] http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/non-english-consent-guide.pdf
[2] http://factfinder.census.gov/faces/nav/jsf/pages/index.xhtml
[3] http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html
[4] http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html
[5] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm
[6] http://irb.ucsf.edu/experimental-subjects-bill-rights
[7] http://irb.ucsf.edu/contact-us
[8] http://hrpp.ucsf.edu/modification
[9] http://irb.ucsf.edu/#reminders
[10] http://irb.ucsf.edu/hipaa
[11] http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/ucsf-hipaa-authorization-research.pdf
[12] http://hrpp.ucsf.edu/sites/hrpp.ucsf.edu/files/SFVAMC-HIPAA-authorization.pdf
[13] https://www.atanet.org/
[14] http://www.atanet.org/onlinedirectories/
[15] http://www.chiaonline.org/
[16] http://www.ncihc.org/
[17] http://www.language-bank.com/
[18] http://www.transperfect.com/
[19] mailto:UCSF@transperfect.com
[20] http://www.nwtranslations.com/
[21] http://www.translate.com/locales/en-US/index.html?init_page=default
[22] http://www.alsintl.com/