

## Guidance and Procedure: Research Involving Non-English Speaking Research Participants (last updated May 9, 2019)

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### Ethical Principles and Regulatory Requirements

*Because the Los Angeles County Area is one of the most culturally and ethnically diverse cities in the country*, investigators who enroll research subjects in Los Angeles and surrounding areas must consider the likelihood of encountering eligible subjects with limited English proficiency. The UCLA community values and respects the cultural and ethnic diversity of our local and national community.

*In order to meet one of the three primary ethical principles of equitable selection<sup>1</sup> of subjects*, non-English-speaking participants may not be routinely excluded from research. In cases where research is of therapeutic intent or is designed to investigate areas that would necessarily require certain populations who may not speak English, the researcher is required to make efforts to recruit and include non-English speaking participants. There are, however, studies in which it would be reasonable to limit subjects to those who speak English, including pilot studies, small unfunded studies with validated instruments not available in other language, numerous questionnaires, and some non-therapeutic studies which offer no direct benefit.

*In order to meet the regulatory requirements for informed consent*, the information must be presented “in a language understandable to the subject” ([45 CFR 46.117\(b\)\(1\)](#) and/or [21 CFR 50.27\(b\)\(1\)](#)) and, in most cases, the consent process must be documented in writing by means of a written consent form ([45 CFR 46.116](#) and/or [21 CFR 50.25](#)). Many of the studies conducted by UCLA researchers will require translations of the consent documents into languages other than English. A look at [the most recent US Census Data for California](#)<sup>2</sup> or other demographic information will help investigators anticipate the languages spoken by potential subjects.

*Researchers should review and be thoroughly familiar with the UCLA guidance for [Obtaining and Documenting Informed Consent](#) and for [Requesting Waivers and Exceptions to Informed Consent](#)*. All these requirements apply for non-English-speaking participants along with the additional requirements described below. webIRB asks whether the study will include non-English-speaking subjects. If not, the researcher may need to provide a scientific, ethical or other reasonable justification for not doing so; the IRB will determine whether the exclusion is acceptable.

### Two Methods for Obtaining Consent from Non-English-Speaking Participants

<sup>1</sup> The Belmont Report, April 18, 1979

<sup>2</sup> 56% of the population in Los Angeles County speaks languages other than English at home. 48% of the population is of Hispanic or Latino origin.

**If a researcher is targeting a non-English-speaking population**, then clearly the consent documents and any related questionnaires or forms for the participants will need to be translated into the target population’s language. Additionally, the researcher or a member (or members) of the research team who speaks the target subject population will need to consent the participants and be available during the study to answer questions and conduct the study.

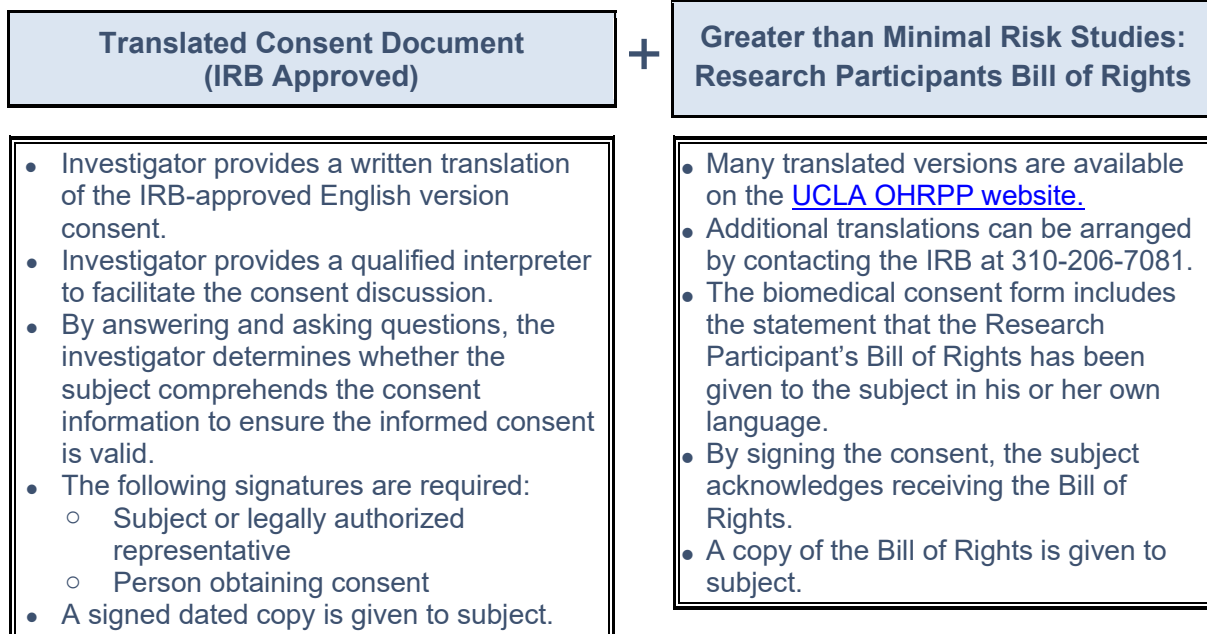
**If a researcher is not targeting a non-English-speaking population**, she or he may need to be prepared to enroll non-English-speaking participants, particularly if the study is therapeutic in nature. Two methods for enrolling non-English-speaking subjects when not targeting this population are described below: **the Preferred Method, and the Short Form Method**. For either of these methods, **a qualified interpreter** will need to be available during the consent process, and to answer questions and conduct procedures during the study.

## Preferred Method

**In the Preferred Method, the researcher:**

- **Discusses in the webIRB application** the goal to target or accommodate non-English-speaking participants;
- **Obtains valid written translations** of the English version of the IRB-approved consent document(s) in anticipated common languages *after the study is approved* (in case IRB requests changes in the documents);
- **Submits translated consent materials** to the IRB as an amendment before enrolling subjects.
- **For biomedical studies**, understands that California law requires that the Research Participant’s Bill of Rights be provided in a language in which the subject is fluent. This document is available in over 30 translations on the [OHRPP website](#).
- **Secures a qualified interpreter** who speaks both English and the participant’s language to be available to answer questions throughout the study.

### PREFERRED METHOD



## Short-Form Method

The **Short-Form Method** should be used only for the occasional and unexpected enrollment of a non-English-speaking subject in a study for which no consent form in the subject's language has been prepared **and** there is no time to obtain a written translation of the IRB-approved English version consent. Instead of signing the English-language consent form (which the subject does not understand), the subject is presented with and asked to sign the Research Participant's Bill of Rights in his/her native language. **Routine use of the "short form" consent method is not permitted!**

***In the Short Form Method, the researcher:***

- **Discusses in webIRB application** the goal to accommodate non-English-speaking subjects.
- **Uses the** ["Short Form Consent Method Checklist"](#) to assure all requirements are met.
- **Secures a qualified interpreter** who speaks both English and the participant's language to obtain, document consent and sign the consent form.
- **Checks the [OHRPP website](#)** to see if there is a Research Participants Bill of Rights translated into the language that is needed.
  - If there is, adds the following three items to the form:
    - *"The elements of consent from the consent form were presented orally."*
    - *"Signature of Participant (or Legally Authorized Representative) and Date"*
    - *"Signature of Interpreter/Witness and Date"*
  - If there is not, arranges for a certified translation of the Participant Bill of Rights into the participant's language, and adds the above three items to the form.
- **Gives a signed and dated copy** of the "short form" to the subject along with a signed and dated copy of the English version of the consent form.
- **Secures a qualified interpreter** who speaks both English and the participant's language to be available to answer questions throughout the study.
- **If study is ongoing**, provides a translated consent form in the participant's language and secures a qualified interpreter to be available to answer questions throughout the study.
- **Submits a Post Approval Incident Report** to the IRB to notify them of the use of the short form method.
- **At the time of Continuing Review**, summarize any and all uses of the short form.

## SHORT FORM METHOD

### English Language Consent Document (IRB Approved)

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### Research Participants Bill of Rights (In the participant's language)

- Investigator provides a qualified interpreter to present the informed consent information orally and to facilitate the consent discussion.
- By answering and asking questions, the investigator determines whether the subject comprehends the consent information to ensure the informed consent is valid.
- The following signatures are required:\*

  - Interpreter/Witness
  - Person obtaining consent

- A signed and dated copy is given to the subject.

- The Bill of Rights written in a language in which the subject is fluent serves as the “short form.”
- Many translated versions are available on the [UCLA OHRPP website](#).
- Additional translations can be arranged by contacting the IRB at 310-206-7081.
- Write a statement on the Bill of Rights that the elements of consent from the consent form were presented orally.
- The following signatures are required:
  - Subject or legal surrogate
  - Interpreter/Witness
- A signed and dated copy is given to the subject.

### IMPORTANT NOTES FOR USE OF THE SHORT FORM:

- **Routine use of the “short form” consent method is not permitted.** University policy is consistent with both FDA and the DHHS regulations.
- **The types of studies for which the short form consent method are appropriate are limited:**
  - Examples of the types of **studies which are likely appropriate:**
    - **A therapeutic study** for a subject whose language was not anticipated and for which there is not sufficient time to translate the consent form.
    - **A minimal risk study** for which there is a short window to enroll a subject and, again, there is not sufficient time to translate the consent form.

#### **Example of Minimal Risk Study for Which Short Form Method Would Be Appropriate:**

Patients with agammaglobulinemia (i.e. lacking all immunoglobulins) are very rare, but are essential in understanding the role of natural antibody in innate immunity. The research procedure is a minimal risk blood draw (to obtain a sample of blood that lacks all natural antibody but has the other components of innate immunity). Standard care is to administer gamma globulin to patients with agammaglobulinemia, but after that has been done, their blood can no longer be used to study the role of natural antibody in innate immunity.

It would be inappropriate to delay gamma globulin transfusion for the time required to develop a translated consent form. If such a subject were otherwise eligible but did not speak English or another anticipated language, then the research is simple enough and the risks low enough that it would be appropriate to use a short form consent process.

## Translated Consent Documents

For initial review, researchers should discuss whether or not they anticipate enrolling any subjects who are not fluent in English and if so how those participants will be accommodated. Investigators should discuss whether any of the consent documents will be translated. If so, all recruiting and consent documents should first be submitted in English. This is because the IRB members may ask for revisions in the documents. Once the English versions are approved, the investigator is responsible for having the consent materials translated.

### Preparing Translated Consent Materials:

- The English version of the consent form should follow the UCLA templates.
- The language level of the documents should be at the 8<sup>th</sup> grade reading level or lower.
- The translations should be valid. There are various methods of validating translations:
  - A professional translation service may be used. See links below in references.
  - 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 may translate the document.

**IMPORTANT NOTE:** “Back translations” are not required or recommended as they do not necessarily reflect a valid original translation.

### Costs of Translating Written Consent Materials:

The cost of translating written consents is the investigator’s responsibility. These costs may be high, particularly for large studies where multiple languages are needed and/or studies with relatively complex consent information that may require additional time by a skilled professional. Investigators should include the costs of written translations as well as qualified interpreter services on grants and contracts. Industry sponsors are often willing to pay for the costs of translating consent forms.

## Providing a Qualified Medical Interpreter

For clinical research, the medical and technical information discussed during the initial consent discussion, as well as ongoing, study-related information, can be very complex and should be communicated to non-English speaking subjects through an interpreter with training and understanding in medical terminology. In addition, an individual with a professional commitment to maintain strict confidentiality should handle the private medical issues discussed with subjects.

### Identifying Qualified Medical Interpreters:

- The interpreters may be a knowledgeable member of the research team who is fluent in English and the language of the participant.
- Interpreter, translation and deaf services are available through the [UCLA Health System Interpreter/Translation and Deaf Services program](#).
- Information about medical interpreters is available from professional organizations including:
  - The American Translators Association maintains a [Directory of Translation and Interpreting Services](#).
  - [The California Healthcare Interpreter Association \(CHIA\)](#) has formulated [standards and protocols](#) for medical interpreters.
  - The [National Council on Interpreting in Health Care \(NCIHC\)](#) provides [a guide](#) for assessing medical interpreters.

**IMPORTANT NOTES:**

- Avoid the use of ad hoc interpreters.
- Do not ask children to serve as an interpreter.
- Consider issues of privacy if family members are asked to translate.
- If an adult family is asked to translate they must be qualified to translate (e.g., health professional and/or knowledgeable of medical terminology)

**Working Effectively with Medical Interpreters:**

The field of medical interpretation is evolving and although protocols are being developed, standardized practices do not exist. Investigators may want to discuss some or all of the following topics with the interpreter before participating in an interpreter-mediated consent discussion.

- Will the medical interpreter serve as patient/subject advocate as well as interpreting the consent material?
- If the English version is presented orally for the alternative “short form” method, how will the interpreter incorporate cultural considerations into the consent information?
- How transparent will the interpreted conversation be? With three people communicating (subject, investigator and interpreter), will everything said by each person be translated?
- How will the investigator and interpreter determine whether the subject truly understands the consent information?
- 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?

**References and Resources**

- [The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research](#), The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, April 18, 1979
- DHHS Office for Human Research Protections [“Obtaining and Documenting Informed Consent of Subjects Who Do Not Speak English”](#) 1995
- FDA Information Sheets: A Guide to Informed Consent, [“Non-English Speaking Subjects”](#)
- Healthcare Interpreting
  - [National Council on Interpreting in Health Care](#)
  - [A Guide for Assessing a Healthcare Interpreter](#)
  - [California Healthcare Interpreting Association](#)
  - California Standards for Healthcare Interpreters: Ethical Principles, Protocols, and Guidance on Roles & Intervention available through [The California Endowment](#)
- [Culture & Clinical Care](#), edited by Juliene G. Lipson, Suzanne L. Dibble, and Pamela A. Minarik, UCSF Nursing Press, 2005.
- [United States Census Bureau \(California QuickLinks\)](#)

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**Change history:**

2019/5/9: Removed requirement for interpreter signature for use of translated consent document