

**Guidance and Procedures Number: 26**

**Title: Special Subject Populations: Non-English Speaking Subjects**

**Date of Last Revision: March 6, 2009**

**I. Introduction**

This guidance defines the standards and parameters for the involvement of non-English speaking individuals in biomedical, behavioral and social science research.

**II. Definitions**

A. **Informed Consent:** An individual's voluntary agreement, based upon adequate knowledge and understanding of relevant information including risks and benefits, to participate in research.

B. **Non-English-Speaking Individuals:** An individual unable to verbally comprehend spoken English language or read and comprehend documents written in English. The inability to understand English makes it impossible for a prospective subject to meaningfully engage in the consent process and to make an informed decision about participation in research. UCLA will consider such individuals as vulnerable due to the difficulty of ensuring informed consent and, therefore, will apply additional safeguards to protect their rights and welfare (45 CFR 46.111(b) and 21 CFR 56.111(b)).

**III. Policy**

A. Inclusion or Exclusion of Non-English Speaking Subjects

1. UCLA investigators must provide an ethical and scientific justification for excluding non-English speaking subjects from research.
2. Unless an ethical and scientific justification is provided to and accepted by the IRB, UCLA investigators may not exclude non-English speaking subjects from research that may have direct potential benefits.
3. Unless an ethical and scientific justification is provided to and accepted by the IRB, UCLA investigators may not exclude subjects who meet the criteria for participation, but who can not speak, understand or read English.
4. UCLA investigators must plan for populations that are likely to be recruited into the research and translations must be incorporated into the study design to allow for appropriate recruitment and consenting.

B. Consent Documents

1. The regulations require that informed consent information be presented “in language understandable to the subject” and, in most situations, that informed consent be documented in writing. Where informed consent is documented in accordance with 45 CFR 46.117(b)(1) or 21 CFR 50.27(b)(1), the written informed consent document should embody, in language understandable to the subject, all the elements necessary for legally effective informed consent (45 CFR 46.116 or 21 CFR 50.25). Subjects who do not speak English should therefore be presented with an informed consent document written in a language understandable to them. Reliance on an oral translation of the English version of the consent form is not sufficient.
2. Informed consent documents must be available in English and other languages as appropriate to the subject population. UCLA investigators will develop consent documents in the language that is most easily understood by persons they wish to include.
3. A qualified individual must complete the written translation of informed consent documents. When possible, the consent forms will be back translated from the second language back to English as an added measure to ensure that the information is correctly conveyed. Care must be taken to ensure that the translations are made in an appropriate dialect, if applicable.
4. *Written* consent documents must be provided to subjects unless the UCLA IRB/OPRS has approved an oral consent process *and* a waiver of the requirement for subjects’ signed informed consent in accordance with 45 CFR 46.117(c) or 21 CFR 56.109(c)(1). The IRB will consider whether to provide a written summary of the information provided orally when waiving the requirement to obtain written documentation of consent. Please see [HRPP Guidance & Procedure #29: Informed Consent Process and Documentation](#) for details.

#### C. Consent Process

1. UCLA investigators must engage potential subjects in a consent process which comprises an informed dialogue about the nature of the research, its risks and benefits. This consent process must take place in a language that the subjects understand.<sup>1</sup>
2. UCLA investigators will be fluent in the subject’s language *or* an interpreter will be available during the consent process and throughout the subject’s participation as needed.
3. A qualified individual who is not a friend or family member of the potential subject and is fluent in both English *and* the subject’s language must perform any necessary oral translation of the consent process (but not as a substitute for a written form in the subject’s language). The individual performing the translation will be known to the investigators, have a professional relationship with the investigators and be available for ongoing communication between subjects and investigators.

#### D. IRB Review of Translated Recruitment and Consent Materials

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<sup>1</sup> 45 CFR 46.116 and 21 CFR 50.20

1. For research in which UCLA investigators expect to include non-English speaking subjects, a consent form translated into the native language of the subjects to be included must be provided to the UCLA IRB/OPRS with the original submission or, if this study population is being added, with the addendum.
  - a. In order to avoid excessive translation costs and reduce the risk of errors, investigators may wish to obtain and submit translated consent forms after the IRB has approved the English version of the consent form.
2. A certified translator should perform the translation and proof of certification should be provided to the UCLA IRB/OPRS along with the translated consent form.
3. For non-medical research where study resources do not permit the use of a certified translator, the UCLA investigator is responsible for obtaining translation services from persons appropriately qualified both in terms of language skills, and of knowledge of research methodology.
4. Any recruitment materials (flyers, radio advertisements, etc.) that have been translated should also be provided to the IRB/OPRS for review and approval.
5. UCLA investigators must translate all study materials that will be distributed to non-English-speaking subjects, such as surveys or questionnaires. Investigators do not need to submit such translated materials to the IRB, but must maintain copies of the translated study materials in their study file, available at any time for audit by the UCLA IRB/OPRS.
6. All recruitment and consent documents translated into a particular language must be submitted to and approved by the UCLA IRB/OPRS before speakers of that language can be consented for participation in the study.

E. Literacy

1. Subjects who meet the criteria for participation and who can speak and understand English, but not read or write it, will not be excluded from participation.
2. Similarly, subjects who can understand and comprehend spoken English, but are physically unable to talk or write, will not be excluded if they are competent and able to indicate approval or disapproval by other means.
3. Both groups of subjects will be included in research studies if they a) can understand the concepts of the study and evaluate the risks and benefits when they are explained verbally and b) are able to indicate approval or disapproval to study entry, either by marking "X" on the consent form or some other means of communication.
4. The consent form will state the method of communication used with the prospective subject and the specific means that the subject used to communicate agreement to participate in the study.
5. When required by the IRB/OPRS, a consent monitor or an impartial third party will witness the entire consent process and sign the consent form. When appropriate, a videotape or an audiotape recording may be used to document the consent process.

#### **IV. UCLA IRB/OPRS Responsibility**

- A. The UCLA IRB/OPRS will ensure that non-English speaking subjects' inclusion and participation in research will be in compliance with federal regulations for the protection of human subjects.
- B. The UCLA IRB/OPRS will ensure that an appropriate informed consent process and materials are reviewed and approved for all research involving non-English speaking subjects.
- C. The UCLA IRB/OPRS will ensure that non-English speaking subjects are not excluded from research that may have direct potential benefits.

#### **V. UCLA Investigator Responsibility**

- A. For each research project, a UCLA investigator must determine whether there is a likelihood that non-English speaking subjects will participate in their research. This is determined based on factors such as research design and requirements, patient demographics, and local area demographics. If non-English speaking subjects are anticipated to participate in the research project, the UCLA IRB-approved consent document for the study must be translated into the language(s) of these subjects prior to their involvement in the research. Translations should include Braille translations for subjects who are blind or visually impaired.
- B. UCLA Investigators are responsible for complying with all elements of this guidance, as well as all applicable Federal, State, and University policies regarding the inclusion of non-English speaking persons in research.
- C. During the conduct of a research project, if a non-English speaking potential subject is encountered who speaks a language which the UCLA investigator did not anticipate, and in which the UCLA IRB-approved consent document has not previously been translated, the UCLA investigator must have the UCLA IRB-approved consent document translated into the unanticipated language and the translated consent document must be submitted to and approved by the UCLA IRB/OPRS *prior to* consenting the individual.

#### **VI. Research Conducted in Other Languages**

- A. When research will be conducted in another language, references in this guidance to English/non-English speakers or readers should be read as encompassing those individuals who do not speak or read the language in which the study will be conducted.
- B. When research will be conducted in another language, investigators are still required to provide the IRB with accurate English-language versions of all study materials. The process of IRB review is conducted based on English-language materials.

**Regulations:**

45 CFR 46  
21 CFR 50 and 56

**References:**

U.S. Office for Human Research Protections' (OHRP, formerly OPRR) *Protecting Human Research Subjects Guidebook (1993)*, Chapter 3. [http://hhs.gov/ohrp/irb/irb\\_chapter3.htm](http://hhs.gov/ohrp/irb/irb_chapter3.htm)

Office for Protection From Research Risks (OPRR, now OHRP) Guidance on *Obtaining And Documenting Informed Consent Of Subjects Who Do Not Speak English*, November 9, 1995. <http://hhs.gov/ohrp/humansubjects/guidance/ic-non-e.htm>

FDA, *IRB Information Sheets: A Guide to Informed Consent*, September 1998. <http://www.fda.gov/oc/ohrt/irbs/informedconsent.html>