Non-English Speaking Subjects

Overview:

This guidance provides information on methods to be used to obtain the informed consent of human subjects who do not speak or understand English.

Federal regulations (45 CFR 46.116 and 21 CFR 50.20) require that researchers obtain the legally effective informed consent of the research subject or their legally authorized representative (if they are not able to consent for themselves). As a consequence, all information provided to potential subjects should be in a language that is understandable to those individuals.

The Belmont Report identifies “justice” and “respect for persons” as two fundamental ethical principles that must underlie the conduct of all human subjects research. The principle of justice requires that the burdens and benefits of research are equitably distributed and calls for “...fair procedures and outcomes in the selection of research subjects.” The principle of respect for persons requires that “adequate standards for informed consent are satisfied” so that potential subjects are provided with sufficient meaningful information to decide whether they want to enroll in a research study. The inability to understand English makes it impossible for a person to meaningfully engage in the consent process and to make an informed decision about participation in research.

Federal regulations (45 CFR 46.117 and 21 CFR 50.27) identify two means by which this requirement can be met:

- Use of a consent document that is translated into a language that is understandable to the potential subject (or their legally authorized representative) OR
- Use of an IRB-approved “short form” consent document, written in a language that the person understands and that is combined with an oral presentation of the English version of the consent document using an interpreter.

When enrolling non-English speaking research subjects, investigators must have a plan to manage communications with the person during all phases of study participation. This includes study visits as well as possible phone calls (e.g., when subjects or family members request information about side effects, drug doses, general questions). This management plan should be described in the IRB application as part of the procedure used to obtain consent.

Definitions:

Non-English speaking – unable to verbally comprehend spoken English 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.
Interpreter – person who accompanies researchers to convey verbal information to another person in their native language

Translator – person who converts written materials from English to another language

Back translation – process of translating written materials from one language to another and then in a separate process translates back into the original language. This process is performed to evaluate the quality and integrity of the information being translated.

Description:

Method 1: Written Translation of IRB-Approved Documents

If the study design explicitly targets the enrollment of non-English speaking subjects, investigators are required to provide a written translation of the IRB-approved consent form and other relevant study documents (e.g., assents, authorizations, questionnaires, dosing instructions) in a language understandable to those participants. It is highly recommended that the documents first be submitted to the IRB in English, and once approved, be sent to the translator. It may be very costly if documents are initially submitted to the IRB with the foreign translations and then changes are requested thus requiring another translation.

1) Submit the English version of the consent form and other required study documents that will be presented to subjects (e.g., study information sheets, recruitment materials, surveys and questionnaires, etc.)

2) Once IRB approval is obtained, submit the documents to the translator
   a. Translation and back translation is required to ensure accuracy of the information
   b. It is the investigator’s responsibility to ensure that the back translation is an accurate representation of the IRB approved English documents.

3) Submit a Modification to the IRB for approval of the following:
   a. English version of relevant documents and translated version
   b. Certification of Translation (document available below in “Additional information” section)

4) Signatures and documentation of consent process
   a. Investigator and subject sign the consent form
   b. Interpreter may be interacting in person, by phone or video-conferencing and does not need to sign the consent form
   c. Participation of all subjects must be documented on the consent form and in the research record
Method 2: Short Form

This method is used when the approved study does not target non-English speaking subjects but the study staff identifies a potential subject who does not understand English. If a full translation of study documents is not available, an alternate procedure, using a written “Short Form” consent along with an oral presentation, is permitted. Note, however, if additional non-English speaking subjects will subsequently be approached for enrollment, the IRB application must be modified and a translated consent form submitted (Method 1).

1) Selected “Short Forms” are available in several languages on the IRB website. If the “Short Form” needed is not displayed, contact the IRB office for assistance.
   a. Identify an interpreter who reads, speaks, and writes the native language of the participant
   b. Identify a witness to the oral presentation who is fluent in the native language of the potential subject as well as fluent in English. Witness must attest to the adequacy of the consent process and the subject’s voluntary consent (21 CFR 50.27b2)
      i. The interpreter (who is not a member of the research team) may serve as the witness
   c. Prepare a written summary of what is orally communicated to the subject by the translator, and give a copy of this to the subject.
      i. The IRB-approved English consent form may serve as this summary

2) Submit an Exception request for IRB approval
   a. Principal investigator can submit the Exception request from the approved study workspace
   b. May not enroll the participant until approval is granted

3) Signatures and Documentation
   a. “Short Form” document
      i. Subject and Witness (interpreter may serve as the witness) sign the consent
   b. Written summary in English
      i. Investigator signs this document
   c. Research Record
      i. Investigator lists names of all individuals who participated in the consent process
Considerations:

**Communication:** When enrolling non-English speaking subjects, it is important to remember that ongoing communication is essential and extends from recruitment to study completion. One must plan appropriately to ensure an interpreter is available for recruitment and consent processes, study visits, and for those unexpected phone calls.

**Translations:** It is important to obtain back translations of documents since differences in dialects, meanings/interpretations, and misinterpretation of words may occur. This is why the IRB requires both the translated document and back translation to ensure appropriate interpretation. In addition, all translations require the completion of the translator certification form to ensure this individual has the appropriate credentialing to perform this function. Since translation services can be costly, obtain IRB approval for the English versions and then send for translation. You will need to submit a Modification to obtain IRB approval for use of the translated documents but it will minimize your expenses. Note: no subjects can be enrolled using these translated documents they have been uploaded into OSIRIS and IRB approval has been obtained. For minimal risk studies, it is permissible for appropriately qualified members of the research team to translate the documents.

**Interpreter:** A common question asked is who can serve as the interpreter. This individual must be fluent in the subject’s language and be unbiased. If the project is a clinical study, the investigator must ensure this individual has extensive understanding of medical terminology. It is important that the person serving as interpreter protects the confidentiality of any information discussed with the subject. Depending on the study, the investigator or study team member who is fluent in the language may serve as the interpreter. The best practice is to have someone independent of your research team perform this function; it may be appropriate to use a member of the clinical staff who is bilingual. Family members are not permitted to serve as the interpreter because they may substitute their views for those of the potential subject.

**Back Translation:** The IRB must have the opportunity to review the written materials being provided to the participants to ensure the accuracy of the translated versions. Depending on the scope, complexity, and risk/benefit of the research, the IRB may require an independent back translation. That is one person performs the translation to the participant’s native/foreign language and another person performs the back translation into English without viewing the original English version.
**OSIRIS application: sections and activities to be addressed**

1. All non-English documents provided to the IRB must include a version translated in English. This applies to supporting documents such as site authorizations, ethic committee minutes/approval letters or other communications.
2. All foreign-language documents must be translated into English and both versions must be uploaded to the designated sections in OSIRIS and not placed in the Supporting Documentation section.
3. The Principal Investigator is responsible for all materials and information provided to subjects which includes ensuring the accuracy of all translated documents.

**Expedited or Full Board review and translated consent form** will be used:

- Section 2; Research and Design Methods (including information about foreign sites, and permission to access those sites)
  - Question 2.19
- Section 3; Human Participants
  - Question 3.4
- Section 4; Subject Recruitment (process and materials) and Informed Consent Procedures
  - Questions 4.1 (recruitment) and 4.12 (consent)
  - Section 4, question 4.9: Upload both the English version and translated version for watermarking (IRB #, approval/expiration dates) – Translated consent forms can be uploaded in WORD or PDF formats. If other formats are used, please contact irb@pitt.edu for assistance
- Supporting Documentation (last section of application)
  - The only documents to be uploaded into this section are the back translations of consent forms and scripts.

**Expedited or Full Board review and “Short Form”** will be used:

- **Requesting an Exception** - prospectively deviating from your approved IRB protocol (now enrolling non-English speaking subject)
  - Go to the approved study workspace
  - Click on located on left side of page under My Activities
    - Answer the questions and submit
    - Reviewed by the IRB and if granted, an approval letter will be sent

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3. The Principal Investigator is responsible for all materials and information provided to subjects which includes ensuring the accuracy of all translated documents.
Exempt review:

- Complete the section on the Exempt form that addresses enrollment of non-English speaking subjects
  - If the investigator is not fluent in the local language, the IRB requires that a local collaborator is identified to be present during the consent process and the research activities to ensure adequate communication between the investigator and the subject
- Upload English versions of all foreign-language documents

Additional Information:

- A Guide to Informed Consent- FDA Information Sheet

- Belmont Report

- Department of Health and Human Services, 45 CFR 46
  [http://www.hhs.gov/ohrp/policy/ic-non-e.html](http://www.hhs.gov/ohrp/policy/ic-non-e.html)

- Translation Certification Form

- U.S. Food and Drug Administration, 21 CFR 50