

GUIDANCE NUMBER 22

GUIDANCE ON CONSENTING NON-ENGLISH SPEAKING SUBJECTS

Section 5 of the RU Guidance

Consenting Non-English Speaking Subjects

The regulations pertaining to the protection of human subjects require that informed consent information for research must be presented in "language understandable to the subject," and, in most situations, that informed consent be documented in writing (**45 CFR 46.116, 45 CFR 46.117 and 21 CFR 50.20**). Regulations allow oral presentation of informed consent information; however, it must be done in conjunction with a short form of written consent document that states that the consent has been presented orally and there must be a written summary of what is orally presented. Likewise, FDA regulations (**21 CFR 50.25 and 21 CFR 50.27**) require that informed consent information be presented in a language understandable to the subject and in most situations, that informed consent be documented in writing.

A witness to the oral presentation is required and the subject must be given copies of the short form document and the summary. For studies that will need the consent translated into another language (subjects may insist), the standard operating procedure is to hold the translation until the IRB has approved the English language consent form. Once the IRB has approved the consent form, a foreign language consent form can then be prepared and the following needs to be resubmitted for final approval of the foreign language consent form.

- A. Original English version of the consent.
- B. Foreign language version of the consent.
- C. A back translation from the foreign language back to English.
- D. A letter or a memo indicating that this translation was done by a different translator than the one who did the original translation.
- E. A letter describing the qualifications (e.g., Spanish speaking native or Vietnamese speaking native) of each translator and date of translation.
- F. Points D and E above may be written in the same letter.

The reason for the back translation is to make sure that the foreign language version contains all of the key elements of the English version. It is proper to anticipate that the back translation may not match word to word, but it is IRB's responsibility to make sure that key elements of the original consent is not left out in the foreign translation.

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.

Unexpected Enrollment of a Non-English-Speaking Subject

Individuals who are unable to verbally comprehend spoken English or read and comprehend documents written in English are considered non-English speaking subjects. Since such subjects are unable to understand English, it makes it impossible for a prospective subject to meaningfully volunteer and make an informed decision about participation in research. Such subjects may also

require the assistance of an interpreter or translator to make an informed decision to participate in the study.

If a non-English speaking subject is unexpectedly eligible for protocol enrollment, there may not be an existing IRB-approved written translation of the consent document. In such cases:

- A. Investigators should carefully consider the ethical and legal ramifications of enrolling subjects when a language barrier exists;
- B. If the subject does not clearly understand the information presented at the signing of the consent document or in subsequent discussions, his/her consent may not be informed, and therefore, not effective;
- C. If a PI decides to enroll a subject into a protocol for which there is not an existing IRB-approved informed consent document in the prospective subject's language, the PI must receive IRB approval to follow the procedures for oral consent. A short English version of the informed consent document translated into the language the subject understands can be used to obtain consent and witness. Such short forms must be submitted to the IRB, the Chair shall determine whether such forms can be used;
- D. 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 and
- E. An alternate to this could be the use of a "Short Form". Contact the IRB Office to receive instructions for the use of a Short Form. A translator may assist in describing the contents in the native language of the subject. A witness must attest to the adequacy and voluntariness of the consent **(21 CFR 50.27(b)(2))**.

Use of Interpreters in the Consent Process

Unless the investigator is fluent in the prospective subject's language, an interpreter will be necessary to facilitate the conversation. Interpreter is preferably someone who is fluent in both English and the subject's language. The interpreter also facilitates the question-and-answer phase of the consent process between the potential subject and the researcher (if the researcher is not the interpreter).