

Participation by Subjects Not Fluent in English

Per federal regulations, the consent process and documents as well as study-related documents (e.g., survey instrument, medical release forms) for participants not fluent in English must be presented in a language (preferably native) understandable to them. If it is expected that participants who do not speak English will be enrolled in a study, translated documents should be made available.

The IRB must approve non-English language versions of written or oral consent documents and all survey instruments as a condition of approval under 45 CFR 46.117(b)(2).

To avoid the need for multiple translations and ease the burden of translation on the PI, it is recommended that only the English language version of the documents be included in the initial submission of the protocol. In this way, the translations need only be completed after the IRB has approved the English version. Generally, the greater the risk to the subject, the greater the assurance of accuracy must be. For very low-risk protocols, for example, the IRB may only require that the translation of the written document be accomplished by someone with demonstrated fluency in both languages. Approval will then be withheld pending receipt of the appropriately translated documents, and may be reviewed and approved by the Chair of the IRB or the Chair's designee. If an additional risk for the non-English-speaking participant is identified, the translation(s) will be referred to the convened IRB for review and approval. The PI is responsible for covering the cost of the translation. The cost of the translation will not be incurred by the participants.

The Office for Human Research Protections (OHRP) allows either traditional written consent procedures or the "short form" written consent procedure which allows for oral presentation. The two procedures are described below. Written consent is the procedure preferred by OHRP. The IRB will determine which procedure and method is appropriate depending on the risk to the subjects.

A. Informed Consent

1. Traditional written consent procedures:

In this procedure, all elements of the English version of the informed consent document must be translated into the written non-English language version, paying careful attention not only to the accuracy of the translation, but the level of understanding of the subject population, as well as any cultural elements specific to the population. Procedures for ensuring accurate translation should be described in detail.

The IRB recommends the use of one of two methods for translation. The **first** method is *back-translation*, where consent forms are first written in English, then translated into the subjects' language, and then back into English. The translation back into English should be done by someone unaffiliated with the research team and unfamiliar with the original English version.

The names and credentials of the persons conducting each step should be provided to the IRB. This method is preferred, particularly for protocols and consent forms that are somewhat complex, difficult to understand, etc. Also, depending on the scope, complexity, and risk-benefit of the research, the IRB may require an independent back-translation.

The **second** recommended method is translation by a *professional translation service* that will attest to the accuracy of the translation.

If one of the two recommended methods is not feasible, the IRB may accept certification from the PI that he/she or a member of the research staff translated the document and that the translation is accurate. This should be explained in the documentation of consent section of the protocol form. An example of appropriate use of this method would be where there are few speakers of the language.

2. Short Form Written Consent:

As an alternative to written documented informed consent, 45 CFR 46.117(b)(2) of the regulations (found at www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html) permits oral presentation of informed consent information. This procedure requires a short form written consent document stating that the elements of consent have been presented orally, as well as a written summary of what is presented orally. Both the oral presentation and the short form written document should be in a language understandable to the subject. The IRB-approved English language informed consent document may serve as the summary. The subject must be given copies of the short form document and the summary. A sample of the short form may be found at www.hhs.gov/ohrp/policy/ic-non-e.html.

45 CFR 46.117(b)(2) also required that the oral presentation must be witnessed by someone who is not part of the research team and is fluent in both English and the language of the subject. When a translator is used who is not part of the research team, the translator may serve as the witness.

At the time of consent:

- (i) the short form document should be signed by the subject (or the subject's legally authorized representative);
- (ii) the summary (i.e., the English language informed consent document) should be signed by the person obtaining consent as authorized under the protocol; and
- (iii) the short form document and the summary should be signed by the witness, certifying that the oral presentation was made to the participant in a language understandable to him/her and described accurately the content of the English-version consent form.

The IRB must receive and approve all non-English language versions of the short form document prior to their use in research. The method of selection of the translator/witness must also be included in the protocol.

B. Research-Related Documents

Materials presented to the subjects, such as surveys, questionnaires, educational materials, advertisements, or other documents, must be translated into a language that those participants understand. They should maintain the same format and convey the same meaning as the original English versions. The translation process should be the same one-way or two-way process described in Section A.1. However, for these materials, the extensive use of a translator to work with the research participant in order to communicate the information in the materials is an acceptable alternative to providing translated documents. The procedures should be fully described in the protocol.