

Guidance on Obtaining and Documenting Informed Consent of Non- English Speaking Subjects

Informed consent information must be presented in language understandable to the subject, and in most situations, informed consent be documented in writing. Investigators should carefully consider the ethical/legal ramifications of enrolling a subject when there is a language barrier. If subjects do not clearly understand the consent document or freely ask and receive answers to their questions, then their consent will not be truly informed and may not be legally effective. Thus, subjects who do not speak English must be provided with: written consent document in a language understandable to them, **AND** translator fluent in both English and the subject's spoken language

Depending upon the research, the written consent document can be either: (I.) a translation of the entire English version of the NYU SoM IRB approved consent document; or (II.) a translation of the so-called "short form."

I. USING A WRITTEN TRANSLATION OF THE ENTIRE ENGLISH VERSION OF THE IRB-APPROVED CONSENT DOCUMENT

Use of a written translation of the entire IRB-approved English version is always preferred. If researchers can reasonably expect that more than an incidental number of subjects speaking the same non-English language will be enrolled (for example, if the investigator is targeting a non-English speaking group), translation of the entire English version is strongly recommended. The IRB must approve all translated versions of the consent form and recommends that the translation be done by a certified translator from Interpreter Services. However, the IRB will consider, on a case-by-case basis, allowing other translators to perform this function with verification that the translation is an accurate and acceptable presentation of the entire English version.

II. USING A WRITTEN TRANSLATION OF THE "SHORT FORM" CONSENT DOCUMENT

Investigators cannot always anticipate the interest of a particular non-English speaking individual and provide him/her with a translation of the entire IRB-approved English version of the informed consent document in a timely manner. Under these circumstances, a translation of the "short form" (which attests that the elements of consent have been presented orally) can be used to document informed consent in writing. When a "short form" is used to document informed consent, the consent process must include oral presentation of the entire English version of the consent form in language understandable to the potential subject. The informed consent process for enrolling subjects using the "short form" consent document is outlined below. **ALL** of the following requirements (1, 2, 3 and 4) must be completed:

1. A translator must orally present the entire IRB-approved English version of the consent form to the subject in a language understandable to him/her, a researcher must be present to conduct the informed consent process and answer questions, and the subject must be given a written translation of the "short form" consent document to read;
2. The entire consent process must be witnessed by an individual who is fluent in both English and the language understandable to the subject. The translator may serve as the witness;

3. The IRB-approved English version of the consent form must be signed by the investigator authorized by the IRB to obtain consent and the witness to the consent process, and the translated "short form" must be signed by the subject and the witness to the consent process (see 2 above); **AND**
4. The subject must be given copies of both the IRB-approved English version of the consent form and the translated version of the "short form" consent document. The original signed English version with the original signed "short form" attached should be placed in the subject's research record and a copy of both placed in his/her medical record, if appropriate.

III. "SHORT FORM" CONSENT DOCUMENT AND TRANSLATIONS INTO COMMONLY ENCOUNTERED LANGUAGES

IRB approved "short form" consent documents are available on the IRB web page. All other translations of the "short form" must be submitted to the IRB for approval. The consent documents are available as "PDF" files and can be printed with Adobe Acrobat.