Policy on Enrolling Non-English Speaking Subjects

For research in which investigators expect to enroll non-English speaking subjects, a consent form translated into the native language of the subjects to be enrolled must be provided to the IRB with the original submission or, if this study population is being added, with the amendment. A certified translator should perform the translation and proof of certification should be provided to the IRB along with the translated consent form.

Any recruitment materials (flyers, radio advertisements, etc.) that have been translated should also be provided to the IRB. In addition, investigators should translate all study materials that will be distributed to non-English-speaking subjects, such as surveys or questionnaires, and submit these to the IRB when the translated consent is submitted.

The translated documents must be approved by the IRB before non-English speaking subjects can be enrolled into the study.

Note that the exclusion criteria in certain protocols may specifically exclude non-English-speaking subjects from participating. Check your full written protocol for inclusion/exclusion criteria before enrolling non-English speaking subjects.

What if investigators encounter a potential subject who is Non-English-speaking, but do not already have a translated consent?

In some cases, a non-English speaker may be eligible for a study for which there is no translated consent document, and for which the study investigators could not have foreseen enrollment of a potential subject who speaks that language. In this case, the federal regulations allow investigators to enroll the potential subject using a "short form" consent that has been translated into the subject's native language.

The consent process must involve a translator who can verbally translate the information in the full written informed consent into the subject's native language. This translator must sign the full written informed consent as well as the short form consent to document that he or she participated in the consent process and that the subject has been fully informed regarding the study. A witness to the translation must also sign the consent form; the translator may him/herself function as the witness.

Like the translated full written consent document, the IRB must approve the translated short form consent prior to its use. However, expedited review of an amendment to approve a translated short form consent is possible if the IRB has previously approved both the protocol in question and the protocol's full English-language informed consent document.

The IRB has approved a short form consent document and has had this consent translated into several languages. If the translated form is not available from the IRB, the
investigator is responsible for obtaining a certified translation. Please see the “Policies and Procedures” page for more information on available translations.