Consent of Non-English Speaking Participants

If the PI is planning to enroll non-English Speaking Participants, then ***both*** of the following must be done:

1. This requires a translated long version of the consent form, any questionnaires, or materials given to participants. This must be reviewed and approved by the IRB prior to their use according to 45 CFR 46. 116 & 117

Documents can be translated via a certified translation service (stamp on consent) or documentation submitted with submission; or

The PI can have the English version translated into language of choice, and a back translation into English done by an independent person. The PI then must make sure that the original English and back-translated version are the same and include a note with the submission that this process was completed.

And

2. This requires that a person fluent (can read and speak the language of choice) be present as a witness to the consent process to verify that the consent was understood.

Person obtaining consent can speak the language of choice, but a witness who is independent of the study and also is fluent in the language must be present to verify that it was informed and not coerced.

The person obtaining consent cannot serve as the witness.

If the PI did not plan to enroll non-English speaking participants and such a participant is eligible for the study, ***ALL*** of the following must be done:

1. Obtain the sponsor's permission to enroll, if the eligibility criteria excluded non-English speaking participants (waiver).
2. A short form that is translated into language of choice must be used (available on IRB website). If this form is available on the IRB website, then it does NOT need IRB review. If this form is not on the IRB website, then it DOES need IRB review prior to use.
3. A translator must be present to translate the long English form into language of choice.
4. A witness must be present to verify that the consent was informed and not coerced.
5. An amendment to the protocol should be submitted to the IRB reporting: 1) a protocol deviation (change in the enrollment criteria), and 2) that a non-English speaking participant was enrolled.
6. If the short forms are used 4 to 6 times in a study, the protocol should be amended changing the eligibility criteria and including a translated version of the long consent form.
7. When the protocol is being renewed, the use of the short form consent process should be documented on the Continuation Form.

Please refer to the IRB Policy 9-2 entitled "Informed Consents Involving Non-English Speaking Participants" located on the IRB website at www.irb.wayne.edu.