WAYNE STATE UNIVERSITY

HIC Policy/Procedure

Wayne State University Human Investigation Committee	
SUBJECT	Informed Consents Involving Non-English Speaking Participants
Section	
Form Date	08-23-06
Approvals	9/18/03 Steering Committee, 9/19/03 Administrative

Background

All research participants must sign an informed consent in a language they can understand.

An increasing number of research studies in English-speaking countries include participants who may not understand the English language. It is vital that all participants have an opportunity to understand enough about the study and the elements of consent in order for them to make an informed decision about participating in the research study. This means that consent must be obtained using language that non-English-speaking participants understand. To implement this requires either written translation or oral presentation in the relevant non-English language by a person who is fluent in both English and the other language.

If it is known in advance that a language other than English will be spoken by the potential study population, an informed consent, in the language of the consenting participant, must be submitted to the HIC with the protocol materials for review and approval.

If it is not known in advance that a potential participant does not speak English, a short form of the informed consent in a language understandable to the participant must be available and used. The participant would be required to sign the written short form in addition to being provided with a written summary of the research in the English languageThe basic regulations are stated in 45 CFR 46.116 and 117 a and b.

Procedures for Informed Consent

Long Form Consent: The Long Form Consent should be used when it is known in advance that a research participant who does not speak and understand English may be enrolled in the research protocol. The

consent form for non-English-speaking participants or legal representatives shall be the same as for English-speaking participants or legal representatives in content and format, except that the non-English consent form will be tranlated into the language that is understandable by the participant or legal representative. The translation process can be accomplished using one of two methods:

1) A two-way process where a) a forward translation of the consent from English to non-English by a translator who is fluent in both languages and b) a back translation into English by a different translator who is fluent in both languages, and who has not seen the original English consent form. An independent review by the PI and IRB is then done to determine the adequacy and completeness of the translation.
2) A 1-way translation of the English consent into the non-English version by a certified process. The IRB will accept a certified version of the translated consent document without a back translation being required.

Written Short Form Consent: A written Short Form Consent should be used when it is not anticipated in advance that a non-English speaking research participant eligible for enrollment in the research partocol. Multiple uses (approximately 4-6) of the written Short Form Consent in the same language should be an indication that a written Long Form Consent should be developed and approved by the IRB. A written short form consent must contain a statement that the basic elements of the consent were presented to the participant or legal representative in a language that was understandable to him/her. The HIC maintains approved copies of the written Short Form Consent on the HIC web site for use by all investigators who did not anticipate the need to enroll a non-English speaking research participant. When properly completed by the investigator, the written Short Form Consent may be used without prior approval by the IRB. If the written Short Form Consent in a language understandable to the research participant is not provided on the HIC web site, the HIC must approve the written short form before it can be used to obtain consent from a non-English speaking research participant. The language of the short form must be understandable to the participant or legal representative.

When the HIC has not provided a written short form in a language that is understandable to the research participant, the translation process shall be:

1) A certified translation from English to non-English by a translator who is fluent in both languages. This translation should be submitted to the IRB for approval.
2) A 2-way process that includes: a) a forward translation from English to non-English by a translator who is fluent in both languages is done and b) a back translation by a different translator who is fluent in both languages, and who has not seen the original English consent form. This version of the Short Form Consent must be reviewed by the PI for accuracy and then sent to the IRB for approval.

The signature of a witness is required on the form. It should be signed by the participant or legal representative, the witness, and translator. (Although the signature of the translator is not specifically required on the Written Short Form by federal regulations, this requirement is determined by the WSU IRB as a method to document the name of the translator for the participant or legal representative.) The translator may serve as a witness. A copy of the signed short form consent and a copy of the approved version of the English consent form should be given to the participant or legal representative.

Translator: This person should be fluent both in English and the language that is understandable to the participant or legal representative. The translator gives an oral presentation to the participant or legal representative that is understandable to the participant that describes the content of theEnglish version of Informed Consent. If the translator is a member of the research team, he/she may also serve as the person obtaining consent, however, another independent person who understands both languages must sign as the witness. The translator signs the English Informed Consent document and the Short Form Consent.

Witness to the Oral Presentation: This person must be fluent in both English and the language that is understandable to the participant or legal representative in order to be witness to the fact that understandable consent content was being presented and not just that an interaction occurred and signatures were obtained. The witness can be related to, or a close associate of the participant or legal representative if the witness meets the other requirements described in this section, and is acceptable to the subject or legal representative. The witness certifies that an oral presentation was made to the participant or legal representative in the language that is understandable to him or her that describes the content of the English version of the Informed Consent. The witness also may serve as the person obtaining consent, but may not serve as the translator. The witness signs the English version of the Informed Consent and the Short Form Consent.

Person Obtaining Consent: If the person obtaining consent is neither the translator nor the witness, this person may be fluent only in English. If the person obtaining consent is also serving as the translator or the witness, then he/she must be fluent in both English and the language that is understandable to the participant or legal representative.The person obtaining consent must not be related to or a close associate of the participant or legal representative. The function of the person obtaining consent is to supervise the process of obtaining consent, and must be knowledgeable about the research study, so as to be able to answer questions about the study that may be asked by the participant. The person obtaining consent may serve as either the translator or the witness but not both, provided that he/she meets the IRB requirements for those positions. The person obtaining consent must sign the English Consent Form and the Written Short Form in order to document this for the participant or legal representative.

Questionnaries for Non-English–Speaking Participants

General Information

When participants who do not understand the English language are involved in research studies that require answering questionnaires, it is important that those questionnaires are translated into a language that the subjects understand. It is also important that the questionnaires convey the same meaning as the original English version. Otherwise, responses of non-English-speaking participants will not be comparable to responses of those who speak English.

Procedures for Self-Administered Questionnaries

Self-Administered questionnaires for non-English-speaking participants shall be the same as for English-speaking participants in content and format, except that the non-English questionnaires will be translated into the language that is understandable by the subject. The translation process shall be:

a) A 1-way process where a certified translation of the document from English into the language of the participant by a certified translator fluent in both languages is obtained by the PI. This version should be submitted to the IRB for approval.
b) A 2-way process where 1) a forward translation from English to non-English by a translator who is fluent in both languages; and 2) a back translation by a different translator who is fluent in both languages, and who has not seen the original English questionnaire. The PI and the IRB should certified that both translations are accurate.

Procedures on Verbally Administered Questionnaires

Questionnaires that are to be adminstered verbally to non-English-speaking participants shall be the same as for English-speaking participants in content and format, and investigators may choose one of two options for translation that are described below:

1. Translation of Questionnaire-The verbal questionnarie will be translated into the language that is understandable to the participant. This translated questionnaire can be administered to the participant by a person who is fluent in the participants's language, but not necessarily fluent in English. The translation process shall be:
    a. forward translation from English to non-English by a translator who is fluent in both languages;
    b. back translation by a different translator who is fluent in both languages, and who has not seen the original English questionnaire; and
    c. independent review and approval of both the forward and back translations by the WSU IRB.
2. Verbal Administration of the Questionnaire-The verbal questionnaire does not require a written translation into the language that is understandable to the participant. However, verbal administration shall be done by a person who is fluent in both English and the other language.

Other Documents for Non-English-Speaking Participants

If the research involving non-English-speaking participants includes the use of verbal scripts, educational materials, advertisements, or other documents in addition to the consent form and questionnaires, the PI must describe the measures they will take to ensure that the information in these scripts or documents will be conveyed to the subjects accordingly and in an understandable method.