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| Wayne State University Institutional Review Board | |
| Subject | Informed Consents Involving Non-English Speaking Participants |
| Section | |
| Form Date | 08-23-06 |
| Approvals | 9/18/03 Steering Committee, 9/19/03 Administrative, 11/30/11 Administrative Approval, IRB Chairs & Administrative Approval 10/10/2012, IRB Chairs & Administrative Approval 6/23/2014, Administrative 3/15/2018 |

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.

Policy

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 IRB after the submitted consent form is approved and before the study begins. . “Known in advance” means that the PI is targeting a population that is anticipated or likely to have non-English speaking participants.

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 together with a translator reading the consent given to all participants. 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 language. A translator must be available to read the long English version of the Informed Consent form to the participant in the participant's language. The basic regulations are stated in 45 CFR 46.116 and 117 a and b.

Procedures for the Informed Consent Process

Non-English Speaking Status Known in Advance: The study's approved Informed Consent (aka "long form") 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 translated into the language that is understandable by the participant or legal representative.

The translation process can be accomplished by:

- 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. This version of the Consent must be reviewed by the PI for accuracy and then sent to the IRB for approval.
OR by
- 2) A **certified** translation from English to non-English by a translator who is fluent in both languages (no back translation is not required). This translation should be submitted to the IRB for approval

Non-English Speaking Status Not Known in Advance: A written short form consent, together with a translator reading the long form given to all participants, should be used when it is not foreseen to be likely nor anticipated in advance that a non-English speaking research participant will be eligible for enrollment in the research protocol.

Multiple uses (approximately **4 - 6**) of the written short form Consent in the same language is an indication that a written long form Consent (the version given to the other participants) needs to be submitted to and approved by the IRB via an amendment.

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 IRB maintains approved copies of the written short form consent on the IRB 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 it is one of the version available on the IRB website. If a written short form consent

that is in a language understandable to the research participant is not provided on the IRB web site, the Investigator must submit to the IRB the form via an amendment and the IRB must approve the written short form before it can be used. The language of the short form must be understandable to the participant or legal representative.

When the IRB 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 (no back translation is not required). This translation should be submitted to the IRB for approval.

Or

- 2) 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. This version of the 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 not 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 entire content of the English 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 considered to be an acceptable witness by 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 consent form in order to document this for the participant or legal representative.

Questionnaires 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 participants 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 Questionnaires: 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.
OR
- 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 Questionnaire: Questionnaires that are to be administered 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:

1. Translation of Questionnaire- The verbal questionnaire 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 participants accordingly and in an understandable method.