



I. Policy

A. Introduction

An increasing number of research studies include subjects who may not understand the English language. It is imperative that all subjects, irrespective of their knowledge of English, have an understanding of the study and the elements of consent that is sufficient for deciding whether or not they participate in the research. This means that consent must be obtained using language that non-English-speaking subjects 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, and who understands both cultures. The basic requirements are stated in the federal regulations (45CFR46), but specific rules for implementation are determined by the MUSC IRB.

B. Federal Regulations on Informed Consent

1. **45CFR46.116 “General Requirements for Informed Consent”**
“...The information that is given to the subject or the [legal] representative shall be in language understandable to the subject or representative...”
2. **45CFR46.117 “Documentation of Informed Consent”**
46.117(a) “Except as provided in paragraph (c) of this section [waiver of documentation], informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject’s legally authorized representative...”

46.117(b) “...the consent form may be either of the following:
 - a) “A written consent document that embodies the elements of informed consent required by 45CFR46.116...” or
 - b) “A short form written consent document stating that the elements of informed consent required by 45CFR46.116 have been presented orally to the subject or the subject’s legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall

approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.”

C. MUSC IRB Policy on Informed Consent

1. Consent Form Option #1: Long Form Written Consent Document

a) Translation Process for the Long Form:

The consent form for non-English-speaking subjects or legal representatives shall be the same as for English-speaking subjects 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 subject or legal representative. The translation process is described below:

- (1) Forward translation from English to non-English by American Translators Association (ATA) certified translator or IRB-approved equivalent; and
- (2) Submission of English and non-English consent; and
- (3) Invoice or written statement by the translator for the translation service.

b) Qualifications for Translators

The IRB protocol must contain a description of the qualifications of each translator to verify that he/she is both bilingual and bicultural.

c) Consenting Process When Using the Long Form

A person who knows the study, its procedures and its scientific basis shall be available by telephone or in person to answer questions before the subject signs the translated consent form. If this knowledgeable person is not fluent in both English and the subject’s primary language, a second person who is fluent in both languages shall be present to translate questions and answers for the person.

2. Consent Form Option #2: Short Form Written Consent Document

The federal regulations at 45 CFR 46.117(b)(2) and 21 CFR 50.27(b)(2) permit the use of a short form consent document stating that the required elements of informed consent have been presented to the subject or the subject's legally authorized representative orally, with a witness present. Within MUSC use of a short form consent document is largely limited to situations where English is not understandable to a potential research subject who is considering whether to participate in a research study, and the investigator does not have an IRB-approved consent document translated into a language understandable to the potential subject.

An IRB-approved short form template is available for use in the above-described instance. Within 30 days of the subject's consent, an amendment translating the long form consent into the subject's language must be submitted to the IRB and the subject must be re-consented using the translated long form at his/her next study visit.

a) Written Short Form Consent

- (1) Content: A statement that the basic elements of consent (as detailed in 45CFR46.1116) were presented to the subject or legal representative in a language that was understandable to him or her.
- (2) Language: Understandable to the subject or legal representative. The translation process shall be as outlined in I.C.i.a above.
- (3) Approval: By the MUSC IRB.
- (4) Witness: Required.
- (5) Signed by: Subject or legal representative, Witness, and Oral Presented. (Note: Although the signature of the Oral Presenter is not specifically required on the Written Short Form by the federal regulations, this requirement is determined by the MUSC IRB as a method to document the name of the Oral Presenter for the subject or legal representative.)
- (6) Copy: To the subject or legal representative.

b) Written Summary of the oral consent presentation

- (1) Content: The basic elements of consent (as detailed in 45CFR46.116) to be presented orally to the subject or legal representative. In studies where there is a consent form for English speaking subjects or legal representatives, the content of the Written Summary shall be the same as that of the consent form.
 - (2) Language: English.
 - (3) Approval: By the MUSC IRB.
 - (4) Signed by: Witness and Oral Presenter.
 - (5) Copy: To the subject or legal representative.
- c) Translator
- (1) Language: Bilingual so that the presentation is understandable to the subject or legal representative.
 - (2) Relationship: Not related to, or a close associate of, the subject or legal representative.
 - (3) Function: Gives an oral presentation to the subject or legal representative in the language that is understandable to him or her that describes the content of the Written Summary. The Translator also may serve as the Person Obtaining Consent, provided that he/she meets the IRB requirements for Person Obtaining Consent, as described in I.c.2.e) below, but may not serve as the Witness. (Note: Although not specified by federal regulations, these dual roles have been determined by the MUSC IRB.)
 - (4) Signatures: Signs the Written Summary and the Written Short Form. (Note: Although the signature of the Translator is not specifically required on the Written Short Form by the federal regulations, this requirement has been determined by the MSUC IRB as a method to document the name of the Translator for the subject or legal representative.)
- d) Witness to the Oral Presentation
- (1) Language: Bilingual so that the presentation is understandable to the subject or legal representative. (Note: Although it is not specified by the federal regulations that the witness be bilingual, this

requirement has been determined by the MUSC IRB. Otherwise, the Witness would not be a witness to the fact that understandable consent content was being presented to the subject or legal representative, but rather, the Witness would be only a witness to the fact that an interaction occurred and that the subject or legal representative signed the document.)

- (2) Relationship: The Witness can be related to, or a close associate of the subject or legal representative if the Witness meets the other requirements described in this section, and also is acceptable to the subject or legal representative.
- (3) Function: Certifies that an oral presentation was made to the subject or legally authorized representative in the language that is understandable to him or her that describes the content of the Written Summary, which contains the basic elements of consent. The Witness also may serve as the Person Obtaining Consent, but may not serve as the Oral Presenter. (Note: Although not specified by federal regulations, these dual roles have been determined by the MUSC IRB.)
- (4) Signatures: Signs the Written Summary and the Written Short Form.

e) Person Obtaining Consent

- (1) Language: English, if the Person Obtaining Consent is neither the Translator nor the Witness. If the Person Obtaining Consent is serving also as either the Translator or the Witness, then he/she must be both bilingual.
- (2) Relationship: Not related to, or a close associate of, the subject or legal representative.
- (3) Function: Supervises 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 subject. The Person Obtaining Consent also may serve as either the Translator or the Witness but not both, provided that he/she meets the IRB requirements for those positions (as outlined in I.C.2.c and I.C.2.d, respectively). (Note:

Although not specified by federal regulations, these dual roles have been determined by the MUSC IRB.)

- (4) Signatures: Signs the written Summary and the Written Short Form. (Note: Although the signature of the person Obtaining Consent is not required specifically on the Written Short Form by the federal regulations, this requirement has been determined by the MSUC IRB as a method to document the name of the person obtaining consent for the subject or legal representative.)

D. Questionnaires for Non-English-Speaking Subjects

1. Introduction

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

2. MUSC IRB Policy on Self-Administered Questionnaires

Self-administered questionnaires for non-English-speaking subjects shall be the same as for English-speaking subjects 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 is described below:

- a) Forward translation from English to non-English by American Translators Association (ATA) certified translator or IRB-approved equivalent; and
- b) Submission of English and non-English consents; and
- c) Invoice or written statement by the translator for the translation service.

3. MUSC IRB Policy on Verbally Administered Questionnaires

- a) Verbal Questionnaire Option #1: Translation of the Questionnaire

The verbal questionnaire will be translated into the language that is understandable to the subject. This translated questionnaire can be administered to the subject by a person who is fluent in the subject's language, but not necessarily fluent in English. The translation process shall be as outlined in Section B2 above

b) Verbal Questionnaire Option #2: Verbal Administration of the Questionnaire

The verbal questionnaire does not require a written translation into the language that is understandable to the subject. However, verbal administration shall be done by a bilingual and bicultural person, and a second bilingual and bicultural person must witness the verbal administration to ensure that the meaning of the original English is being translated accurately.

E. Other Documents for Non-English-Speaking Subjects

If the research involving non-English-speaking subjects includes the use of verbal scripts or documents other than the consent form and questionnaires, then the investigators 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 way.