RESEARCH INVOLVING NON-ENGLISH-SPEAKING PARTICIPANTS

11/20/2023

1. Informed Consent for Non-English-Speaking Participants

There is an increasing need to include in research studies those participants who may not understand the English language. It is imperative that all participants, regardless of their knowledge of English, have an understanding of the study and the elements of consent that are sufficient for deciding whether or not to participate in a research study. This means that consent must be obtained using language that is understandable to the non-English-speaking potential participant. This process requires either written translation and/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.

A. Acceptable Methods for the Consent of Non-English-Speaking Participants

The DUHS IRB recognizes two methods for obtaining the consent of non-English-speaking research participants:

(1) Use of Translated Long Form Consent Form (preferred method)
(2) Use of Translated Short Form Consent Form

B. Use of Long Form Consent Form

This method requires translation of the English consent form by either a valid translation service or individual(s) who are known by the Principal Investigator (PI) to be bilingual. A valid translation service is defined as a well-established business entity or an entity that is regularly utilized by Duke in other areas that require translation.

The IRB submission must contain the following:

(1) forward and back translations of the consent form by two different individuals (e.g., translators)
(2) a statement concerning the qualifications of the translators. If the translation is done outside of a translation service, then the statement should include an attestation by the PI that both translators are bilingual.
(3) a description of the consent process that clarifies who will do the oral presentation in the potential participant's spoken language and the presenter's qualifications for the role. The presenter must be bilingual. Ideally, the presenter will also possess sufficient knowledge of the study to be able to address any questions concerning its design, risks, benefits, costs, etc. However, if such an individual is not available, the presenter may translate the potential participant's questions to a qualified study team member who is present and, in turn, back-translate their replies to the potential participant.
(4) a description of who will sign the long form consent form. This should be signed by the participant and the study team member obtaining consent. The consent process

should be documented to include the translator's name and that the long form consent form was used in the participant's spoken language.

Required: two bilingual translators, oral bilingual presenter.

Exception: When conducting research in an international location and all human subjects interaction is subject to the review of a local IRB (see the International Research Policy), the IRB submission may contain English and local language versions of the consent form(s), in addition to the local IRB approval notice indicating that the consent form(s) were also reviewed by that IRB.

Other exceptions to these requirements must be prospectively approved by the DUHS IRB.

C. Use of Short Form Consent Form

This method also requires translation of the IRB-approved English consent form by either a valid translation service or individual(s) who are known by the PI to be bilingual. Please refer to the Short Form Consent Policy for additional information.

The IRB submission must contain the following:

(1) forward and back translations of the consent form by two different individuals (e.g., translators) *NOTE: Not required when using the template short form consent forms posted at irb.duhs.duke.edu.* The short form consent must be signed by the participant, presenter, and a bilingual adult witness. The **adult witness** may be a family member or friend of the potential participant but **NOT** a member of the study team or an individual having a familial or reporting relationship to a study team member. DUHS IRB recognizes that there may be complex studies where a bilingual clinician with a reporting relationship to a study team member may be an appropriate witness to ensure that the information was accurately conveyed. However, this would be an exception to the preferred standard, and this person could not be a member of key personnel for the study. Rationale for this should be documented in the consent process section of the IRB application.

(2) a statement concerning the qualifications of the translators. This should include an attestation by the PI that both translators are bilingual.

(3) a description of the consent process that clarifies who will do the oral presentation in the potential participant's spoken language and the presenter's qualifications for the role. It is required for the presenter to be bilingual. Ideally, the presenter will also possess adequate knowledge of the study to be able to address any questions concerning its design, risks, benefits, costs, etc. However, if such an individual is not available, the presenter may translate the potential participant's questions to a qualified study team member who is present and, in turn, back-translate their replies to the potential participant.

(4) an English translation of the script of the oral presentation. The script must contain all elements required for valid consent. The PI may submit the English long form version of the consent form as the script.

Required: two bilingual translators, oral presenter, adult witness

Exceptions to these requirements must be prospectively approved by the DUHS IRB.

2. Questionnaires/Surveys for Non-English-Speaking Participants
When participants who do not understand the English language are involved in research studies that require responding to questionnaires or participating in surveys, it is important that those questionnaires are translated into a language that the participants understand. Also, it is important that the questionnaires convey the same meaning as the original English version.

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 to the participant. The translation process shall require one forward and one back translation by two bilingual translators either from a valid translation service or by individuals known to the PI to be qualified to assume this role. As with consent form translation, the research summary within the iRIS application must contain either the name of the translation service or the names of the two individual translators accompanied by an attestation from the PI regarding their qualifications to assume this role.

3. Focus Groups/Interviews for Non-English-Speaking Participants
Focus groups and interviews must be conducted in a language that is understandable to non-English-speaking participants and must be of a format and content similar to that of the original English versions. These activities must be conducted by an individual who: (1) is bilingual; and (2) possesses extensive knowledge of the research study, such as a study team member. If this is not possible, the DUHS IRB may approve a strategy where the focus group/interview is conducted by an English-speaking study team member through a bilingual translator. Although not required, it is recommended that the focus group/interview be audio-recorded, then transcribed into English by a second independent bilingual translator.

4. Adverse Events, Research Questions and the Right to Withdraw
When enrolling non-English-speaking participants into a research study, the PI must make provisions during the course of the study for the participant to report adverse events or ask questions in their spoken language. Likewise, there must be a provision for the participant to withdraw from the study at any time by expressing verbally or in writing the wish to leave in their spoken language. The IRB submission for the study should include a description of this process.

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