Washington University in St. Louis

10/4/12
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Obtaining and Documenting Informed Consent of Participants who Do Not Speak English

I. Researchers must carefully consider the ethical/legal ramifications of enrolling participants when a language barrier exists.

a. If the participant does not clearly understand the information presented, the participant's consent will not truly be informed and may not be legally effective. This participant should not be enrolled.

b. If the participant needs a translator at the time of enrollment, will a translator be available for each subsequent visit and/or interim contact for example by phone? If the answer is "no," the participant should not be enrolled.

c. Who will the qualified translator be? Ideally this will be an impartial person with high health literacy in both English and the other language. Typically, this is not a family member.

Do you anticipate enrolling more than one non-English speaker? If yes, consider modifying your study to include non-English speaking individuals.

II. Inclusion of Non-English Speakers is Anticipated using Written Consent

When the researcher expects that the study participant population will include non-English speaking individuals or that the consent process will be conducted in a language other than English, the IRB requires that the information is given to the participant or their representative in a language understandable to the participant or representative. In these situations, the consent form or information sheet (if the requirement for a signature is waived) must be translated by a qualified translator to the language(s) appropriate for the participants. The translated document(s) must be submitted to and approved by the IRB prior to use. A copy of the translated consent document (signed and dated) or information sheet must be given to each participant.

While a translator may be helpful in facilitating conversations with a non-English speaking participant, routine ad hoc translation of the consent document should not be substituted for a written translation. In addition, any other assessments or documents that the subject will read and/or complete need to be translated, and submitted to the IRB for approval prior to use. The research team should have in place procedures to communicate with the subject throughout the conduct of the study including should the subject call with questions or concerns.

III. Inclusion of Non-English Speakers is Not Anticipated

If a non-English speaking participant is unexpectedly encountered, the researcher should first consider the issues identified in section I of this document. If the researcher believes it is appropriate to enroll the subject given these considerations, the consent "short form" process must be used. (see 21 CFR 50.25 and 45 CFR 46.117.)

1. Subjects may only be enrolled who speak one of the languages represented in the list of currently translated short forms below.
2. Identify a qualified translator (typically not a family member.)

3. The translator must orally translate verbatim the IRB-approved English consent document or information for the study.

4. The participant (or legally authorized representative) reads the approved "short form" written consent document, in a language the participant understands. The short form must be one provided on the HRPO website from the list below. This form documents that the required elements of informed consent were presented orally.

    a. The subject or their representative signs the short form.
    b. A witness signs the short form. The witness cannot be a member of the research team and should be fluent in both English and the language of the participant.
    c. The member of the research team who obtained consent signs the English consent document.
    d. The witness signs the English consent document.

    Note: if using the BJC Refugee Health and Interpretive Services, the policy is to have a witness that is different from the interpreter. The BJC Refugee Health and Interpreter will not sign as a witness. Therefore, the interpreter does not need to be in the room, you can call the On-call interpretive service 24 hours a day, 7 days a week at 314-747-5682.

5. Following signatures, copies of the English consent document/information summary and the short form are provided to the subject or their representative.

6. For studies that involve more than minimal risk and or involve longitudinal followup, ideally and as soon as available, the research team should submit a translated consent document/information summary to the IRB for approval. Once approved, this document should be provide to the participant who was consented using the short form process.

    Although the PI should strive to present a consent document written in a language understandable to the non-English speaking participant, this is only strongly encouraged by OHRP. It is acceptable per the federal regulations to use oral consent with a short form and a copy of the English version consent.

Translational Services:

- For information regarding interpreter services at WUMC, please contact Barbara Bogomolov, Refugee Health and Interpreter Services at 314-747-5683.
- Language Access Metro Project (LAMP), 24/7 interpreter services, 866-948-7133.

WU IRB Approved Short Forms

The following short form consent documents have already been approved by the HRPO.

English version for translation
Arabic
Bosnian
Burmese
Chinese
Dari
Farsi
French
German
Japanese

Kurdish
Nepali
Russian
Somali
Spanish
Vietnamese

To obtain these short form versions go to http://hrpo.wustl.edu/research-toolkit/investigator-guide/

References:

45 CFR 46.116 and 46.117
21 CFR 50.20
21 CFR 50.27
FDA Information Sheets, “A Guide to Informed Consent”
http://www.fda.gov/oc/ohrt/irbs/informedconsent.html#nonenglish
OHRP Short Form guidance. http://ohrp.osophs.dhhs.gov/humanparticipants/guidance/ic-non-e.htm