Instructions for Research Involving Non-English-Speaking Participants

I. Instructions for Obtaining and Documenting Informed Consent

Federal regulations require that informed consent information be presented "in a language that is understandable to the participant." Discussions with participants about their participation in the trial should be conducted with an interpreter who is fluent in both English and the language of the participant. Arrangements with interpretation services should be arranged ahead of time, if possible. The interpreter may be a member of the study team. Family members should not, if possible, serve as the interpreter.

There are currently two accepted procedures for obtaining consent from non-English speaking participants:

Option 1: ***Federal regulators and the DFCI IRB strongly encourage the use of this procedure whenever possible:*** If a study team plans on enrolling non-English speaking study participants, the entire consent document, with the exception of the header and footer, should be translated into a language understandable to participants. (Translation of the footer or the header is unnecessary as this information will be filled in by OHRS prior to being posted on OncPro. Additionally, the Phrase "Not for Subject Use" found in the header of unofficial versions is included in the header of non-English consent form documents and is not translated) The translated document must be approved by the IRB. This is typically done after initial IRB review of the English consent form. Once the English form is approved, the form should be translated to the relevant language and submitted to OHRS as an amendment along with a certificate of translation.

Once IRB approved, the translated version of the consent must be signed by the participant (or legally authorized representative). The individual obtaining informed consent must sign the English consent. The investigator or person obtaining the consent should provide an oral explanation of the study with the assistance of an interpreter. A witness is not required.

Option 2: Investigators cannot always anticipate the interest of a non-English speaking individual and therefore may not be able to obtain an IRB-approved translated consent document in a timely manner. In such cases, the regulations do permit the use of a "short form." The short from is written in a language understandable to the participant and sets out the basic requirements for informed consent.

Posted on the OHRS website are short forms and short form addendums available in 24 languages.

Please follow these guidelines when utilizing the "short form" method:

- The role of the interpreter is to interpret between the investigator and the prospective participant. The interpreter should not be asked to do a sight translation of the long IRB approved English consent document.

- The role of the investigator is to participate in the session at which the interpreter

is present by: (1) using the English long form informed consent document as the source from which the investigator summarizes the research for the interpreter; and (2) answer questions the prospective subject may pose to the investigator through the interpreter.

- When a prospective subject does not speak English, it is strongly recommended that informed consent is obtained with the assistance of an interpreter rather than a family member. While family members are often very willing to assist, they may inadvertently bias an interpretation based upon how they wish the prospective subject to view participation in the research.

- The short form must be accompanied by a written summary of what is presented orally (the IRB-approved English language consent document may serve as the written summary). The participant or the legally authorized representative should be given copies of both signed documents.

- The interpreter may serve as the witness. When an interpreter signs as a witness they are confirming that "an oral presentation" of the long form English consent document was conducted. The interpreter does not witness the understanding of the prospective participant.

- Signature Requirements:

    - Short Form (in participant's language):
        - Signature of participant or legally authorized representative (required by OHRP/FDA)
        - Signature of witness (required by OHRP/FDA)
    - English Informed Consent Document:
        - Signature of person obtaining consent (OHRP)
        - Signature of witness (required by OHRP/FDA)

- The consent process must be appropriately documented in the participant's medical/research record.

- Special Requirements for Optional Studies: If a study contains optional studies, the participant is assumed not to have consented to these unless the short form has an additional section included to capture the participant's responses to participation in those Optional Studies. Please use the applicable translated version of the "Addendum for Optional Studies" for this purpose and ensure that it is signed by the participant or the legally authorized representative, as well as a witness. Translated addendums are available on the OHRS website (http://www.dfhcc.harvard.edu/research/clinical-research-support/document-library-forms-sops-etc/ohrs-form-library/#shortform).

II. Instructions for Ongoing Participation

- The study team should arrange for an interpreter to be present for study visits, as appropriate, since the informed consent process is an ongoing process and additional questions may arise after the initial informed consent document has been signed.

- Verbal questionnaires must be administered by an interpreter.

- Written questionnaires, participant diaries and other participant information sheets must be translated into a language that is understandable to the participant. Translated documents must be submitted to OHRS along with a certificate of translation prior to use. If translated documents are unavailable, the study team must report alternative plans to the IRB as a Deviation.

If you have any questions or need more information, please contact the OHRS at (617) 632-3029.

Additional information is also available from the following websites:

FDA:
A Guide to Informed Consent, Non-English Speaking Participants
http://www.fda.gov/oc/ohrt/irbs/informedconsent.html

OHRP:
Obtaining and Documenting Informed Consent of Participants Who Do Not Speak English
http://www.hhs.gov/ohrp/policy/ic-non-e.html