Instructions for Obtaining and Documenting Informed Consent of Non-English Speking Subjects

Federal regulations require that informed consent information be presented "in a language that is understandable to the subject." Discussions with subjects about their participation in the trial should be conducted with an interpreter who is fluent in both English and the language of the subject. The 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 subjects:

Option 1: ***Federal regulators and the LSUHSC 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 should be translated into a language understandable to the participants. The translated document must be approved by the IRB. This is typically done at the time of initial IRB review. The translated version of the consent must be signed by the subject (or legally authorized representative), and the individual obtaining informed consent. The investigator or person obtaining the consent should provide an oral explanation of the study with the assistance of an interpreter.

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 form is written in a language understandable to the subject and sets out the basic requirements for informed consent.

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

- The role of the interpreter is to interpret between the investigator and the prospective subject. The interpreter should not be asked to do a sight translation of the long IRB approved English consent document.
- 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 written summary embodies the basic and required additional elements of disclosure. The subject should be given copies of both documents.
- The interpreter signs as a witness that "an oral presentation" of the long form English consent document was conducted. The interpreter does not witness the understanding of the prospective subject.
- Signature Requirements:
  - Short Form (in subject's language):
    - Signature of subject 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)

For non-English speaking study participants, the witness is conversant in both English and the language of the participant. The interpreter may serve as the witness. The consent process must be appropriately documented in the subject's medical/research record.

If you have any questions or need more information, please contact the IRB office at 504-568-4970.

Additional information is also available from the following websites:

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

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

Information and foreign language consents courtesy of Dana Farber Cancer Institute.