OBTAINING AND DOCUMENTING INFORMED CONSENT OF SUBJECTS WHO DO NOT SPEAK ENGLISH

The Department of Health and Human Services (DHHS) regulations (45 CFR 46.116 and 45 CFR 46.117) and FDA regulations (21 CFR 50.25 and 21 CFR 50.27) require that informed consent information be presented in language understandable to the subject, and in most situations, that informed consent be documented in writing. Given the diversity of patients seen in our hospitals, investigators may encounter a non-English speaking patient who is interested in participating in a research study. When presented with this situation, investigators should carefully consider the ethical and legal ramifications of enrolling a subject when there is a language barrier. It is neither ethically justifiable to exclude potential subjects in a research study solely on the basis of language spoken nor ethically justifiable to obtain consent of subjects who do not have a clear understanding of the consent document or who do not have the opportunity to freely ask and receive answers to their questions. Without this understanding and opportunity, consent may not be truly informed and may not be legally effective. In order to address these considerations, when enrolling subjects who do not speak English in research, the subject must be provided with **BOTH**:

- a written consent document in a language understandable to them, AND
- an interpreter fluent in both English and the subject's spoken language

Depending upon the research, the *written* consent document can be either:

- a written translation, in the subject's language, of the entire English version of the consent form approved by the Partners Human Research Committee (PHRC), OR
- a written translation of the so-called 'short form' consent document

The 'short form' should generally only be used when the research involves no more than minimal risk to subjects or, if more than minimal risk, presents the prospect of direct benefit to individual subjects.

USE OF A WRITTEN TRANSLATION OF THE ENTIRE ENGLISH VERSION OF THE PHRC-APPROVED CONSENT DOCUMENT

When investigators can reasonably expect that more than an incidental number of subjects speaking the same non-English language will be enrolled (for example, if the research is targeting a non-English speaking group), the use of a written translation of the *entire* English version of the consent form is required. The PHRC must approve all written translated versions of the consent form and recommends that the written translation be done by an in-house medical translator from Interpreter Services or other qualified person or service recommended by Interpreter Services. Investigators must also arrange for a medical interpreter fluent in both English and the subject's spoken language to be present, or available by phone or videoconference, during the consent process.

USE OF A WRITTEN TRANSLATION OF THE 'SHORT FORM' CONSENT DOCUMENT

Although it is always preferable, and in some cases required by the PHRC, to use a written translation of the *entire* PHRC-approved English version of the consent form (see above), a translated version of a 'short form' consent document can be used to document informed consent when a non-English speaking individual is unexpectedly encountered and a written translation of the PHRC-approved consent form is not available. The 'short form' consent document should generally only be used when the research involves no more than minimal risk to subjects or, if the research involves more than minimal risk, presents the prospect of direct benefit to individual subjects. The 'short form' attests that the elements of

consent have been presented orally. When the 'short form' is used to document informed consent, the consent process must include oral presentation of the English version of the consent form in a language understandable to the potential subject. A medical interpreter must be physically present to interpret, in the subject's language, the researcher's oral presentation of the English version of the consent form.

The consent process for enrolling subjects using the 'short form' consent document is outlined below. **ALL** of the following requirements must be completed:

1. The Principal Investigator (or other member of the study staff with PI-delegated responsibility for obtaining informed consent) must present the PHRC-approved *English version of the consent form* orally to the subject through a medical interpreter physically present and fluent in English and the language understandable to the subject;
2. The subject must be given a written translation of the *'short form'* consent document in the language understandable to him/her to read;
3. The entire consent process must be witnessed by an individual who is fluent in both English and the language understandable to the subject. The interpreter may serve as the witness to the consent process (presentation of the information in the consent form in the language understandable to the subject and the opportunity to ask and receive answers to questions);
4. The PHRC-approved *English version of the consent form* must be signed by the investigator obtaining informed consent **and** the witness to the consent process (see 3 above);
5. The written translation of the *'short form'* must be signed by the subject **and** the witness to the consent process (see 3 above); and
6. The subject must be given signed copies of **both** the PHRC-approved *English version of the consent form* **and** the written translation of the 'short form' consent document.
7. The original signed *English version of the consent form* with the original signed written translation of the '*short form'* document attached should be placed in the subject's research record. A copy of both forms should be placed in the subject's medical record, if the information is relevant to their medical care.

The PHRC requires that the interpreter come from the pool of experienced medical interpreters available through Interpreter Services. The PHRC will consider approving an exception to the requirement to use an interpreter from Interpreter Services on a case-by-case basis.

AFTER INITIAL CONSENT

Because informed consent is an ongoing process, issues related to the subject's ability to understand and ask questions should continue to be considered throughout the study, and not just at the time of initial consent. For example, it is recommended to arrange for a medical interpreter to be available at subsequent study visits to ensure that subjects have an opportunity to ask questions and receive relevant study information.

'SHORT FORM' CONSENT DOCUMENT AND TRANSLATIONS INTO COMMONLY ENCOUNTERED LANGUAGES

Below are HRC approved 'short form' consent documents. All other translations of the 'short form' must be submitted to the HRC for approval.

For more information about short form consent documents and obtaining consent, please visit the links below:

FDA: A Guide to Informed Consent, 1998 Update
OHRP Memorandum: Obtaining and Documenting Informed Consent of Subjects Who Do Not Speak English, 11/09/95

‘SHORT FORM’ CONSENT DOCUMENTS
http://healthcare.partners.org/phsirb/nonengco.htm#BulletIII
Arabic
Chinese
Dutch
French
Greek Spanish
Haitian/Creole
Italian
Portuguese
Russian
Spanish