UNIVERSITY OF TENNESSEE COLLEGE OF MEDICINE CHATTANOOGA INSTITUTIONAL REVIEW BOARD INFORMED CONSENT OF NON-ENGLISH SPEAKING SUBJECTS AND ILLITERATE ENGLISH-SPEAKING SUBJECTS

I. PURPOSE

To outline the procedures for UTCOMC IRB concerning informed consent of subjects who are illiterate or who do not speak English.

II. SCOPE

This SOP applies to the IRB administrator, IRB members and investigators.

Personnel Responsible:

UT COMC/EHS IRB administrator, Board members and investigators.

III. BACKGROUND

Investigators may not involve a human subject in clinical research without the legally effective informed consent of the subject or the subject's legally authorized representative (LAR). Because legally effective informed consent requires adequate comprehension by the prospective subject or the subject's LAR of the key elements of consent information, the informed consent disclosure must be presented in a language understandable to the subject or the subject's LAR. When it is anticipated that subjects or LARs will be involved who do not speak English as their primary language, a foreign language consent form may be reviewed and approved by the UTCOMC IRB. Non-English speaking subjects should not be excluded solely on the basis of language.

In accordance with:

45 CFR 46.109; 21 CFR 50.23(a); 21 CFR 50.20 and 50.25; 21 CFR 56.109 and 56.111; 45 CFR 46.111; 45 CFR 46.116; 45 CFR 46.117

FDA IRB Information Sheets: Guide to Informed Consent, 1998 located at http://www.fda.gov/oc/ohrt/irbs/informedconsent.html

FDA IRB Information Sheets: Frequently Asked Questions on Informed Consent Process and Informed Consent Document Content, http://www.fda.gov/oc/ohrt/IRBS/faqs.html

OHRP Guidance on Informed Consent located at
http://www.hhs.gov/ohrp/policy/index.html#informed

OHRP FAQs on Informed Consent located at
http://www.hhs.gov/ohrp/faq.html

OHRP Guidance on Informed Consent of Subjects Who Do Not Speak English located at http://www.hhs/gov/ohrp/humansubjects/guidance/ic-non-e.htm

Compliance with this policy also requires compliance with state or local laws or regulations that provide additional protections for human subjects

IV. PROCEDURE

All provisions of the UTCOMC IRB Informed Consent SOP apply to this SOP.

1. Non-English speaking subjects: Consent written in language understandable to subject (preferred procedure)

    a. When it is anticipated that subjects or LARs will be involved for whom English is not the primary language, informed consent information and the consent document must be provided in a language understandable to subjects or LARs and contain all elements necessary for legally effective informed consent.
    b. A non-English certified translation of the English version of the IRB-approved informed consent document will be provided for review and approval by the IRB prior to use with prospective subjects.
    c. The persons obtaining informed consent must be fluent in both English and the language of the subject or LAR, or be assisted by a certified interpreter. The interpreter must be designated as such a member of the research team. Family or friends of the prospective subject or LAR may not serve as interpreter.
    d. It is not acceptable for a verbal translation of an English informed consent document to be substituted for a written translation.

    e. Signatures:
        i. The person obtaining consent as authorized by the protocol signs the consent form in the language that he/she understands. If the person obtaining consent speaks the

language of the subject, he/she may sign the foreign language consent.

ii. If a certified translator is utilized, the person obtaining consent signs the English version, the translator signs both the English and foreign language version.

iii. The subject signs the consent is his/her primary language.

iv. When the person obtaining consent is assisted by a translator, the translator may serve as the witness.

v. When the EHS translator phone system is used, the phone translator may not serve as the witness; it must be someone in the room.

f. After the informed consent signature has been obtained, the subject or his/her LAR will be given a copy of the signed informed consent document.

2. Non-English speaking subjects: Use of short form (see algorithm at end of this section;

a. In the event that a non-English speaking subject is unexpectedly encountered and there is not a written translation of the informed consent document, an oral translation may be utilized. The PI must carefully consider the risks associated with the research study and whether the non-English speaking subject fully comprehends the risks and benefits of participation. Failure to fully inform the subject or satisfactorily answer all the subject's questions may render the signature on the consent illegal and certainly constitutes an ethical dilemma.

b. Oral presentation of informed consent information is permitted in conjunction with a short form written consent document (stating that the elements of consent have been presented orally) and a written summary of what is presented orally.

c. A witness to the oral presentation is required, and the subject must be given copies of the short form document and the summary.

i. The oral presentation and the short form written document should be in a language understandable to the subject;
ii. The summary (i.e., the English language informed consent document) should be signed by the person obtaining consent as authorized under the protocol;
iii. The short form document and the summary should be signed by the witness. When the person obtaining consent is assisted by a translator, the translator may serve as the witness.

d. The IRB must receive all foreign language versions of the short form document as a condition of approval under the provisions of 45 CFR 46.117(b)(2). Expedited review of these versions is acceptable if the protocol, the full English language informed consent document, and the English version of the short form document have already been approved by the convened IRB.

e. After the informed consent signature has been obtained, the subject (or LAR) will be given a copy of the signed informed consent document and a full copy of the consent in the English language.

3. Illiterate English speaking subjects

a. Potential subjects who are mentally competent and understand English, but who do not read or write English or are physically disabled may be enrolled in research studies by "making or placing an X" on the consent document in the space for the participant signature after the study information has been reviewed with them.
b. An impartial witness is to be present to attest to the adequacy of the consent process and the subject's voluntary participation.
c. The individual obtaining the consent and the witness must sign the consent document in addition to the subject.
d. Upon verbal explanation, the potential subject should be able to:
i. Understand the concepts of the study;
ii. Understand the risk(s) and benefit(s) of being in the study;

iii. Indicate approval or disapproval to enter the study.

e. The person obtaining the consent should ascertain the above and document the method(s) utilized to communicate with the subject and the method(s) utilized by the subject to communicate agreement to enter the study.

f. A signed copy of the informed consent document shall be given to the subject or his/her LAR.

g. Video and audio taping of the process may be utilized with permission of the individual and in accordance with the institution’s policies.

Consent Process for Non-English Speaking Subjects