

**UNIVERSITY OF TENNESSEE HEALTH SCIENCE CENTER
INSTITUTIONAL REVIEW BOARD
INFORMED CONSENT OF NON-ENGLISH SPEAKING SUBJECTS
AND ILLITERATE ENGLISH-SPEAKING SUBJECTS**

I. PURPOSE

This document outlines the procedures for University of Tennessee Health Science Center Institutional Review Board concerning the informed consent of subjects who do not speak English or who are illiterate speakers of English.

II. SCOPE

This SOP applies to all IRB administrative staff, members and investigators.

Personnel Responsible:

IRB members, administrative staff 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. Because legally effective informed consent requires adequate comprehension by the prospective subject or the subject's legally authorized representative 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 legally authorized representative. When it is anticipated that subjects or legally authorized representatives will be involved who do not speak English as their primary language, a foreign language consent form may be reviewed and approved by UTHSC IRB. Non-English speaking subjects should not be excluded solely on the basis of language.

REFERENCES

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; applicable state and local laws.

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. PROCEDURES

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

Non-English Speaking Subjects:

1. When it is anticipated that subjects or legally authorized representatives 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 legally authorized representatives and contain all elements necessary for legally effective informed consent.
2. A non-English certified translation of the English version of the IRB-approved informed consent document be provided for review and approval by the IRB prior to use with prospective subjects.
3. The person obtaining informed consent must be fluent in both English and the language of the subject or legally authorized representative, or be assisted by an interpreter. The interpreter must be designated as such as a member of the research team. Family or friends of the prospective subject or legally authorized representative may not serve as interpreter.

4. It is not acceptable for a verbal translation of an English informed consent document to be substituted for a written translation.
5. A short version of the informed consent document is not acceptable.
6. The translator, if utilized, individual obtaining consent, subject and witness must sign the document.
7. After the informed consent has been obtained, the subject or his or her legally authorized representative will be given a copy of the signed informed consent document.
8. Methodist Healthcare facilities only:

In the event 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 language line service for MH is the Certified Languages International (1-800-237-8434) and the Patient Affairs Department may be contacted for assistance in accessing this service to assist in translations. The PI must carefully consider the risks associated with the research study and whether the non-English speaking subject fully comprehends or there is a language barrier. Failure to fully inform the subject or **satisfactorily answer all the subjects' questions may render the signature on the consent illegal and certainly constitutes an ethical dilemma.**

If a translator is utilized during the informed consent process, the proceedings should be documented in a language understood by the subject and signed by the translator, witness and subject.

The subject will be given a copy of the signed short form.

Questions about or assistance with the informed consent process should be referred to the MH administration.

Illiterate English speaking subjects:

1. 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.

2. An impartial witness is to be present to attest to the adequacy of the consent process and the subject's voluntary participation.
3. The individual obtaining the consent and the witness must sign the consent document in addition to the subject.
4. Upon verbal explanation, the potential subject should be able to:
 - a) understand the concepts of the study
 - b) understand the risk(s) and benefit(s) of being in the study
 - c) indicate approval or disapproval to enter the study
5. 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.
6. A signed copy of the informed consent document shall be given to the subject or his or her legally authorized representative.
7. Video and audiotaping of the process may be utilized with permission of **the individual and in accordance with the institution's policies.**