UNIVERSITY OF TENNESSEE GRADUATE SCHOOL OF MEDICINE
INSTITUTIONAL REVIEW BOARD
INFORMED CONSENT OF SUBJECTS WHO DO NOT SPEAK ENGLISH

I. PURPOSE

This document outlines the procedures for University of Tennessee Graduate School of Medicine Institutional Review Board (UTGSM IRB) concerning the review and approval of informed consent documents for subjects who do not speak English.

II. SCOPE

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

Personnel Responsible:

UTGSM 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 UTGSM IRB.

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.

Information Sheets: Guidance for Institutional Review Boards and Clinical Investigators, 1998
http://www.fda.gov/scienceresearch/specialtopics/runningclinicaltrials/guidancesinformationsheetsandnotices/ucm113709.htm

A Guide to Informed Consent
http://www.fda.gov/RegulatoryInformation/Guidances/ucm126431.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 UTGSM IRB Informed Consent SOP 005 apply to this SOP.

2. 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.

3. UTGSM IRB requires a certified translation of the English version of the IRB-approved informed consent document be provided for review and approval.

4. 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.

5. All communication and documentation concerning informed consent will be kept in the IRB files for the study.