

**UNIVERSITY OF TENNESSEE HEALTH SCIENCE CENTER
INSTITUTIONAL REVIEW BOARD
INFORMED CONSENT OF NON-ENGLISH SPEAKING SUBJECTS,
ILLITERATE ENGLISH-SPEAKING SUBJECTS, AND VISUALLY-
IMPAIRED OR HEARING-IMPAIRED 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. As a result, when it is anticipated that subjects or legally authorized representatives will be involved who do not speak English as their primary language, a translator must participate in the informed consent interview. In addition, the use of a foreign language consent form will normally be required by the UTHSC 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.

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 located at <http://www.fda.gov/oc/ohrt/IRBS/faqs.html>

OHRP Guidance on Informed Consent located at <http://www.hhs.gov/ohrp/regulations-and-policy/guidance/informed-consent/index.html>

OHRP FAQs on Informed Consent located at <http://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/>

OHRP Guidance on Informed Consent of Subjects Who Do Not Speak English located at <http://www.hhs.gov/ohrp/regulations-and-policy/guidance/obtaining-and-documenting-informed-consent-non-english-speakers/>

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

IV. PROCEDURES

A. 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. See SOP: UTHSC IRB Informed Consent.
1. A non-English translation of the English version of the IRB-approved informed consent document and the Translator's Declaration (http://www.uthsc.edu/research/research_compliance/IRB/consent.php) must be provided for review and approval by the IRB prior to use with prospective subjects.
2. 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, who must be physically present during the informed consent interview. Family or friends of the prospective subject or legally authorized representative may not serve as interpreters.
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. 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.
7. Because informed consent is an ongoing process, an interpreter must be available for all research-related interactions involving subjects or legally authorized representatives who are non-English speaking.
8. Methodist Healthcare (MH) facilities only:

A written translation of the informed consent document is required. 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 the informed consent interview. 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 subject's 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, key research personnel and subject.

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

B. Illiterate English Speaking Subjects

1. Potential subjects who are mentally competent and understand English, but who do not read or write English (i.e., are illiterate), 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. Upon verbal explanation, the potential subject should be able to:
 - a. describe the study procedures in lay terms and appreciate what will be involved in participation in the study,
 - b. understand the risk(s) and benefit(s) of being in the study, and
 - c. indicate approval or disapproval regarding participation in the study.

3. The person obtaining the consent should ascertain the above and document in the research record the method(s) utilized to communicate with the subject and the method(s) utilized by the subject to communicate agreement to enter the study.
4. A signed copy of the informed consent document shall be given to the subject or his or her legally authorized representative.
5. Video and audiotaping of the process may be utilized with permission of the individual and in accordance with the institution's policies.

C. Visually-Impaired English Speaking Subjects

1. Potential subjects who are mentally competent and understand English, but who are visually impaired, 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. If the subject is unable to make an "X" on the signature line, he/she can verbally indicate that he/she consents and can designate a representative (for example, a relative, hospital patient advocate, social worker, etc.) to sign the consent line for him/her, provided the latter party is not involved in the actual conduct of the study. This situation should be explained and documented in the consent discussion notes in the research record, including a description of the identity of the person to whom the authorization has been given.
2. After the consent form has been reviewed, the prospective subject should be able to explain all major elements of consent information that were disclosed in the interview.
3. The person obtaining the consent should ascertain the above and document in the research record the method(s) utilized to communicate with the subject and the method(s) utilized by the subject to communicate agreement to enter the study.
4. A signed copy of the informed consent document shall be given to the subject or his or her legally authorized representative.
5. Video and audiotaping of the process may be utilized with permission of the individual and in accordance with the institution's policies.

D. Hearing-Impaired English Speaking Subjects

1. Potential subjects who are mentally competent and hearing impaired may be enrolled in research studies. The use of a sign language interpreter is permitted and may be necessary if the potential subject cannot read lips or is unable to communicate clearly with the person obtaining consent.
2. After the consent form has been reviewed, the prospective subject should be able to explain all major elements of consent information that were disclosed in the interview.
3. The person obtaining the consent should ascertain the above (via a sign language interpreter if needed) and document in the research record the method(s) utilized to communicate with the subject and the method(s) utilized by the subject to communicate agreement to enter the study.
4. A signed copy of the informed consent document shall be given to the subject or his or her legally authorized representative.
5. Video and audiotaping of the process may be utilized with permission of the individual and in accordance with the institution's policies.