
EFFECTIVE DATE: *March 25, 2022***PROCEDURE TITLE:**

Vulnerable Populations: Obtaining and Documenting Informed Consent of Participants who: Do Not Speak, Read, or Comprehend English; Illiterate; Blind

***To be reviewed every three years by:
Institutional Review Board***

REVIEW BY: *March 24, 2025*

PROCEDURE

This Procedure implements the requirements of Institutional Review Board Policy No. 1 *Authority of the Institutional Review Board*, which requires the Trinity Health Mid-Atlantic (THMA) Institutional Review Board (IRB) establish policies and procedures to ensure that the THMA's IRB operations fully comply with applicable laws, regulations, professional standards, and the *Ethical and Religious Directives for Catholic Health Care Services*, including promoting the conduct of ethical and compliant research.

Investigators who enroll research participants must consider the likelihood of encountering eligible patients with limited English proficiency. Investigators have an ethical and legal obligation to assess the participant's understanding of the consent information to ensure that the consent is truly understood and informing. This obligation increases when the risks are more serious and the research methodology is more complex. When the investigator and participant do not share a language, the investigator must depend on the accuracy of translated consent documents and the working relationship with a medical interpreter. The investigator's familiarity with the participant's culture ("cultural competency") or lack of familiarity affects the communication, engagement and interaction during the entire research effort (treatment and follow up interactions). It is necessary to adapt the preservation of the study information to a participant's capabilities.

Investigators need either to communicate directly with participants, or to provide a reliable alternative to ensure that:

- Study participation is voluntary, as indicated by free and truly informed consent (respect for persons); and
- Study schedules, procedures, and risks are accurately communicated, and participants have ongoing opportunities to express concerns and ask questions, in order to minimize risks to subjects (beneficence); and
- There are fair procedures and outcomes in the selection of research participants so that risks and benefits of research are shared in society (justice).

- When using the short form to document consent, the informed consent must begin with a concise and focused presentation of the key information to assist a prospective participant in understanding the reasons why one might or might not want to participate in the research. This subsection requires that this part of the informed consent must be organized and presented in a way that facilitates comprehension.

Department of Health and Human Services (DHHS) regulations for the protection of human subjects require that informed consent information be presented "in language understandable to the subject" and, in most situations, that informed consent be documented in writing (45 CFR §46.116 and §46.117).

I. Initial considerations for actively seeking recruitment/ enrollment of non-English speaking populations

The new study application and protocol would describe the consent process for non-English speaking participants. Other study documents such as questionnaires, diaries, and HIPAA form will need to be provided in the language that is understandable to the participant.

Informed consent is an ongoing process throughout a study. For non-English speakers, the investigator should address the means for providing continued, qualified interpretive services for the duration of study participation. Likewise, for those who understand spoken English but cannot read, or write, the investigator should be prepared to provide the necessary support to ensure the participant's ongoing comprehension of any new information, or study required action or activities is realized. A participant will need to be able to ask questions and convey information to the investigator regarding possible side effects and other important study information.

It is the investigator's responsibility to judge the participant's comprehension of the consent information including the understanding that participation is voluntary and that the participant has the right to withdraw at any time during the study. If the investigator doubts the participant's consent comprehension, he/she should not enroll the participant in the study.

Investigators and study sponsors should be mindful of translation costs when developing study budgets. Consideration regarding sufficient resources to support the participant during study participation and on-going consent dialog needs to be considered.

II. Translation

A translation is the rendering of a written document (e.g., consent form, questionnaires, diaries, reminder cards) from one language into another; assuring the language of the translated document has the same meaning as the written document in the first language.

A certified translation is one that has been formally verified by a licensed translator or translation company for use in official purposes. Certified translators attest that the target-language text is an accurate and complete translation of the source-language text. Certified translation of consent documents ensures that the tone, meaning and content of the translated documents remain consistent with the IRB-approved English version.

III. Interpreters/Witness

The medical and technical information discussed during the initial consent discussion, as well as ongoing conversations regarding study-related information, can be very complex. Communication with non-English speaking participants should occur through an interpreter with training, experience in healthcare and be knowledgeable of medical terminology. In addition, an individual with a professional commitment to maintain strict confidentiality should handle the private medical issues discussed with participants.

The witness must be an adult, fluent in both languages, who is not a member of the study team (i.e., is not listed in the protocol as an investigator), nor the participant's family or friends. The interpreter may serve as the witness. A witness will be present during the oral presentation of the English version of the IRB approved consent document.

Principal investigators and study team members should consider the following:

Investigators may want to discuss some or all of the following topics with the interpreter before participating in an interpreter-mediated consent discussion. Working with an interpreter to explain complex topics such as randomization, placebo, dosing schedules and invasive/noninvasive procedures may require additional time and/or subsequent discussions.

- Will the medical interpreter serve as patient/subject advocate as well as interpreting the consent material?
- If the English version of the consent form is orally presented and used as the written summary, how will the interpreter incorporate cultural considerations into the consent information?
- How will the investigator and interpreter determine whether the participant truly understands the consent information? Will the interpreter use a "teach back" method?
- What steps will be taken by the investigator to ensure that the participant will continue to understand ongoing study-related communications?
- As with all consent discussions, sufficient time should be allowed for explaining each section of the consent and allow time for the participant to ask questions.

IV. Occasional and Unexpected Circumstances (not prospectively considered at initial review):

In cases when a non-English speaking participant may be eligible for a study for which the study investigators did not plan for enrollment, a "short form" will be used in conjunction with an oral presentation of the full English consent form to the participant by an individual (interpreter) fluent in the participant's language (as required by 45CFR46.116). The short form document will be in the participant's native language.

While it would be ideal for the witness to be in the room, it is not a regulatory requirement. There may be circumstances that will allow the witness to be available via telephone. If the witness/interpreter performs the services on the telephone, his/her signature to the consent may occur by use of facsimile or e-mail.

The translated short form is generic, not study specific. Routine use of the "short form" for obtaining informed consent is discouraged.

V. Documentation

The non-English speaking participant or legally authorized representative will sign and date the short form.

The witness and researcher will sign and date both the short form and the written summary of the oral presentation (the full English consent can serve as the summary of oral presentation).

A copy of the summary of the oral presentation (the full English consent with signatures applied) and the short form, with signatures applied will be given to the participant.

The IRB may determine that additional signatures or documentation may need to be employed.

VI. Illiterate, English-Speaking Participants

A person who speaks and understands English, but does not read and write, can be enrolled in a study by "making their mark" on the consent document, when consistent with applicable state law. A person who can understand and comprehend spoken English, but is physically unable to talk or write, can be entered into a study if they are competent and able to indicate approval or disapproval by other means. If (1) the person retains the ability to understand the concepts of the study and evaluate the risk and benefit of being in the study when it is explained verbally (still competent) and (2) is able to indicate approval or disapproval to study entry, they may be entered into the study. The consent form and study records should document the method used for communication with the prospective participant and the specific means by which the communication occurred. An impartial witness should be present during the entire consent process and sign the consent document.

VII. Blind Participants

If you are enrolling participants who cannot read the consent and other materials due to blindness, or the subject's legally authorized representative is legally blind:

- An impartial witness observe the consent process.
- Sufficient time should be allowed for questions to be asked and answered, both by the blind participant, and by the legally authorized representative.

VIII. Submission to the IRB

The IRB must review and approve the original English document(s), the translated document(s) including the short form, and the reverse translation back to English prior to use. The source and credentials (certification of accuracy or equivalent) of the translator services will also need to be submitted.

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.

It is the responsibility of the IRB to determine which of the procedures are appropriate for documenting informed consent in protocols that it reviews. Various consent processes are employed during a research study and depend invariably on the type of study being done, the type of intervention or methodology employed. The consent process is reviewed initially during review of a new study consideration.

The translated consent forms or other documents must be accompanied by a letter of certification from the translator or translation service to the IRB. This occurs initially or in an expedited fashion. At continuing review the patient/recruitment logs should detail gender, ethnicity/race, and should also specify non-English speaking participants have been consented, recruited or enrolled and indication of the language proficiency. The log should also indicate if there was an illiterate participant enrolled.

RESPONSIBLE DEPARTMENT

Further guidance concerning this Procedure may be obtained from the Trinity Health Mid-Atlantic Institutional Review Board.

APPROVALS

Initial Approval: March 25, 2022

Subsequent Review/Revision(s):