Institutional Review Board
Penn State College of Medicine
Penn State Milton S. Hershey Medical Center

Consent for Limited English Proficient Participants

For research involving targeted populations that have limited English proficiency, the use of a written translation of the approved long form consent document is required. A short form consent documentation process is available for documenting consent when an individual with limited English proficiency is encountered unexpectedly and an IRB-approved translated long form consent document is not available.

- Definition: Limited English Proficient - Persons who do not speak English as their primary language and who have a limited ability to read, speak, write or understand English can be limited English proficient, or "LEP".

- Written translation of long and short form documents - The IRB must review and approve all foreign language versions of consent documents for a particular study prior to use.
    - For long form consent document translations, the investigator may wish to delay translation service until IRB approval is granted for the English version to avoid extra translation costs.
    - For short form consent documents, the IRB web site includes translations in several languages available for use. Versions in other languages will need to be submitted for IRB approval before use.
    - The translation of a consent document must be made by a reliable source.
    - The IRB may request verification of a back translation process by an individual who is not associated with the research to confirm the accuracy of the translated document.
    - The investigator must provide the credentials of the individual(s) or service(s) that were used to translate (and back translate, if applicable) the consent documents. A Certification of Translation form is available on the IRB website for this purpose.

- Short form consent - The short form documentation process should be used when an individual with limited English proficiency is encountered unexpectedly and no translated long form is available. For this process the following are required:
    - Oral presentation of the research in a language understandable to the participant or the participant's legally authorized representative (LAR) by a qualified interpreter
    - A short form consent document in a the participant or LAR's language
    - A written summary of the information that is presented orally (the IRB-approved English language long form consent document may serve as a summary). A witness fluent in both English and the language of the participant or participant's LAR who is present for the oral presentation. The witness is someone who is not involved in the research. When the person obtaining consent is assisted by a qualified interpreter or translator, that individual may serve as the witness if he/she is not involved in the research.

- Providing a qualified medical interpreter - No matter which process (long or short form) is used, it is strongly recommended that a qualified medical interpreter be used for the consent discussion(s) involving individuals with limited English proficiency.
    - The medical and technical information explained during consent discussions and ongoing study communications can be very complex and should be communicated through an interpreter with

training and understanding in medical terminology, and professionally commitment to confidentiality. The IRB web site includes a link to hospital policies for interpretation service requirements and available resources.

- Signatures required -

The following are the requirements for long form consent documents:

- The subject or representative signs and dates the consent document.
- The individual obtaining consent signs and dates the consent document.
- Whenever the IRB or the sponsor require a witness to the oral presentation, the witness signs and dates the consent document.
- For subjects or read who cannot read and whenever required by the IRB or the sponsor, a witness to the oral presentation signs and dates the consent document.
- A copy of the signed and dated consent document is to be provided to the subject.

The following are the requirements for short form consent documents:

- The subject or representative signs and dates the short form consent document and the summary.
- The individual obtaining consent signs and dates the short form consent document and the summary.
- The witness to the oral presentation signs and dates the short form consent document and the summary.
- Copies of the signed and dated consent document and summary are provided to the subject or representative.