11.3 CONSENTING NON-ENGLISH-SPEAKING SUBJECTS

Federal regulations, 45 CFR 46.116 and 117; 21 CFR 50.25 and 50.27, require that informed consent information be presented in a language understandable to the subject, and in most cases that informed consent be documented in writing. Investigators should consider the ethical and legal ramifications of enrolling a subject when there is a language barrier. If subjects do not have a clear understanding of the consent document or are not able to freely ask questions and understand the answers, then their consent will not be truly informed and legally effective. When subjects/families do not speak English, the use of translated consents is always preferred.

A. Translated Consent Forms

If an investigator anticipates that non-English speaking subjects will be enrolled on a study or if the parents or guardians do not speak English, the consent documents should be translated into the native language(s) of potential subjects and/or parents prior to their enrollment. Protocol-specific foreign language consent and assent forms require IRB approval before being used to enroll study subjects. If the investigator does not initially anticipate enrolling non-English speaking subject(s) but later wishes to do so, the consent and assent forms should be submitted as an amendment with the certification of translation. The IRB often requires revision to English Informed Consent Forms as part of the IRB review process. Translated consent forms should therefore not be submitted to the IRB until the English version of the consent form is approved to minimize the number of iterations and translations.

The investigator shall provide the qualifications of the translator to the IRB as well as a translator attestation and/or the certificate from a certified professional translation service as part of the IRB review process. IRB review requirements for translated informed consent documents can vary depending on the level of risk of the research. Translations for minimal risk studies may be approved by the IRB without the use of a professional translation service if the competency to perform the translation (native speaker, credentials, academic degrees, etc.) is otherwise demonstrated and accepted by the IRB. Studies that are greater than minimal risk and/or are biomedical in nature generally require a certificate from a certified professional translator or a "back translation" by a different translator other than the one who performed the original translation.

Translators must be fluent, meaning they speak, write and understand the language that is being translated easily and accurately. Online translation programs (e.g., Google Translate) that offer instant translation are generally not accurate or acceptable for research-related documents. A "back-translation" by a different translator other than the one who performed the original translation is generally recommended but generally not required for minimal risk studies. The IRB may require a "back translation" for minimal risk research studies under certain situations, such as if the study is complex, has complex medical terminology or procedures, or the target population vulnerable. The investigator is responsible for responding to questions and/or providing documentation to the IRB regarding the required elements of the translation.

B. Use of a Translated Consent Form

The informed consent process for enrolling subjects using a translated consent form must meet the following requirements:

i. The investigator must submit the translated document(s) to the IRB for review and approval with a certificate of translation by the translator indicating that the translation is a true representation of the English version.

ii. The PI or person obtaining consent, through the interpreter, must orally present the IRB approved version of the translated consent to the subject, and the subject must be given a written translation of the consent form to read;

iii. Per Institutional policy, every effort should be made to use a professional interpreter as needed. An interpreter must read, speak, and write the native language and English, and be available to answer participant questions at any stage of the study. No patient, family, or friend should be utilized as an interpreter. No child under the age of 18 should ever be asked to interpret or translate documents. If fluent in the language spoken, the principal investigator or another study team member who is authorized to obtain consent, may present the study information directly to the subject/family. . For research involving clinical procedures (e.g., biomedical research and clinical trials) interpreters must have sufficient training and understanding in medical terminology Care should be taken to ensure that the interpreter's relationship with the subject does not adversely influence the subject's ability to make an independent decision regarding participation.

iv. The investigator and/or study staff authorized by the IRB to obtain consent must sign the approved translated version of the consent form;

v. The subject/LAR should sign the translated consent form;

C. Use of a Short Form for Informed Consent

Federal regulations 45 CFR 46.117 (and 21 CFR 50.27) include provisions for a consent process that can accommodate an illiterate subject or a subject who cannot read/understand English. For research studies that may encounter subjects in these situations, the regulations allow for the use of a short form in combination with a verbal presentation of information related to the conduct of the research. The occurrence of the verbal informed consent process is documented via a "short form written consent document" (short form).

The short form states that the elements of informed consent have been presented orally to the subject, and that the key information required by 46.116(a)(5)(i) was presented first to the subject, before other information, if any, was provided. The short form does not contain protocol-specific information and should only be used under special circumstances (e.g., the enrollment of illiterate persons or non-English speakers for whom no translated consent form is available) and enrollment of subjects in a study which requires an immediate decision (due to the emergent nature of the research).

The IRB will consider the complexity of the study and the ability of potential subjects to understand the protocol when presented verbally. The ability to accommodate non-English subjects throughout the course of the research will also be considered to ensure the safety of participants. The IRB must be confident that the research team can readily communicate with participants to assess outcomes and safety.

The use of an interpreter and the "short form" is deemed appropriate for situations where the investigator anticipates that most participants will be fluent in English, however, acknowledges

that occasionally non-English speaking patients may be eligible for a research study. ORIC has provided IRB approved translations of a "short form" in several languages (e.g. Spanish, Bosnian, Vietnamese, Polish, Arabic, Russian, etc.) for investigators which can be downloaded from the IRB website.

The informed consent process for enrolling subjects using the short form must meet the following requirements:

i. The PI or person obtaining consent, through the interpreter, must orally present the IRB approved English version of the consent to the subject in a language understandable to the subject, and the subject must be given a written translation of the short form consent document to read;

ii. Per Institutional policy, a professional interpreter should be utilized in the informed consent process. Care should be taken to ensure that the interpreter's relationship with the subject does not adversely influence the subject's ability to make an independent decision regarding participation. Under no circumstances, should an individual under the age of 18 serve as interpreter;

iii. The consent process must be witnessed by an individual who is fluent in both English and the language understandable the subject. The interpreter may serve as the witness;

iv. The IRB shall approve a written summary of what is to be said to the subject or the representative, typically the IRB approved consent English consent form serves as this summary;

v. The investigator and/or study staff authorized by the IRB to obtain consent must sign the approved English version of the consent form;

vi. The subject/LAR should sign the translated short form;

vii. The witness to the consent process must sign both the translated short form and the summary (English informed consent form);

viii. A copy of both the IRB-approved English consent form (i.e., the summary) and the translated version of the short form must be given to the subject/LAR. Copies of both forms must be placed in the subject's study file and medical record (as applicable).