

consider and plan how these documents will be translated and made available to the subject.

4. Before enrolling a LEP or NEP subject under unexpected circumstances, the Investigator must:
 - a. Submit an amendment if the project requires the subject to speak English as an eligibility criterion.
 - i. The amendment must be approved before an LEP or NEP subject may be enrolled. (If the project is industry-sponsored, the Sponsor's approval of this change must be provided with the amendment).
 - b. Assure that a summary in English of what is to be presented to the subject is

- b. The project staff member going through the consent process should allow the subject time and opportunity to ask questions, and to think over the implications of project participation in accordance with *IRB SOP: Informed Consent Process for Human Subject Research*.
6. Investigators must obtain the subject's signature to document the consent process. In addition, the following required signatures and additional steps in the consent process must be completed:
 - a. The language specific short form should be signed by the subject (or the subject's LAR), the interpreter, and an adult witness.
 - b. The English IRB Approved Consent Form should be signed by the witness and the individual conducting the informed consent discussion.
 - i. The rationale for the use of the witness "Subject has limited English proficiency" should be selected under the witness signature box.
 - ii. A copy of the short form and the English consent form must be provided to the subject. The originals should then be stapled together and filed
 - c. Document the short form consent process followed in Sections A & B in your regulatory file (e.g. using a memo or note to file) and in the subject's medical record if the project is FDA-regulated.
 - d. Submit an amendment to describe the plan for ensuring continued consent and communication with the subject during the project. If additional enrollment of LEP or NEP subjects is expected, the project should be amended at this time, following the process outlined below in Anticipated Recruitment.
 - e. Report the unexpected enrollment of LEP or NEP subjects in the next continuing progress report (CPR) and include a description of the process that was followed and the plan to ensure the continued understanding of the project by the subject.

Anticipated Recruitment and Enrollment of LEP and/or NEP subjects:

1. When project is anticipated to recruit and enroll LEP or NEP subjects, Investigators must identify in the eBridge SmartForm the target populations, the language(s) and must specify who will provide the translation and interpretation and their qualifications. In addition, the eBridge SmartForm must include the following:
 - a. A description of the subject population, the procedures for eliciting informed consent, and the plan for ensuring continued consent and communication with the subjects during the project. The *IRB SOP: Informed Consent Process for Human Subject Research* must be followed.
 - b. The consent form, questionnaires, surveys or other documents that subjects are expected to read and/or complete must be translated into a language that is understandable by the subject.
 - c. The English and translated versions of the documents must be uploaded to the eBridge SmartForm.
 - d. Upload copies of the *Translator's Declaration* and *Back-Translator's Declaration* if applicable. These documents must be completed, signed, and uploaded in support of the translated consent form(s) and recruitment materials to be use.

For Projects enrolling only non-English Speaking subjects:

1. Investigators must provide the proposed consent form and other documents in English and in the language of the subjects.
2. Investigators must provide the *Back-Translator's Declaration* for the consent form(s) and recruitment materials.

Informed consent process

1. Investigators must provide a consent form in a language understandable to the subject. The consent form must follow *IRB SOP: Informed Consent Document for Human Subject Research*. Both the translated consent form, the back translation and the English version must be reviewed and approved by the IRB before use.
2. When conducting the consent process, Investigators should ensure:
 - a. Project team members conducting consent must be familiar with the project and fluent in both English and the subject's primary language, OR
 - b. In addition to the project team member conducting consent, there must be a second individual who is fluent in both languages (not a family member) and who will be present to interpret for the subject to facilitate any questions and answers.
3. Investigators should ensure that an individual who is familiar with the project and fluent in both languages is available by phone or in person to answer questions during the conduct of the project.

Questionnaires and other documents

1. When a project involves questionnaires, surveys, or other documents that subjects are expected to read and/or complete, subjects must be provided the document in their own language. The document must convey the same meaning as the original English version. Otherwise, responses of non-English proficient subjects will not be comparable to responses of those who are proficient in English.
2. Investigators must describe the process for administering the questionnaire or survey in the eBridge SmartForm.

Interpreter and translation services:

For Projects which will enroll Froedtert Health patients

1. When enrolling subjects at Froedtert Health location, the following must be observed when identifying who can serve as an interpreter for a project:
 - a. No minor under the age of 18 can serve as an interpreter.
 - b. Family members cannot serve as an interpreter for a subject
2. The translator for the project's consent form and/or other documents, must be a certified or credentialed translator.

Projects conducted in the community at large (not enrolling from Froedtert Hospital)

1. The following qualifications must be observed when identifying who can serve as an interpreter for a project:
 - a. No minor under the age of 18 can serve as an interpreter.
 - b. Family members cannot serve as the interpreter
 - c. If selecting an interpreter from the community from which subjects will be recruited, a plan to ensure confidentiality must be described in the eBridge SmartForm.
2. When identifying who may serve as a translator or conduct the back-translation for the project consent form and/or other documents, the following qualifications must be indicated:
 - a. A native speaker who holds the equivalent of a high school education
 - b. An individual who holds a degree in the language of the target population(s)
 - c. A certified or credentialed translator.
3. The translated documents must also be back translated into English by a certified or credentialed translator, or other credentialed person (e.g. foreign language degree) acceptable to the IRB. The back-translated documents must be provided in the IRB submission.

- a. The translation and back-translation cannot be performed by the same individual.
4. To ensure that the translated documents convey the same meaning as the original in English, the completed *Translator's Declaration* and *Back-Translator's Declaration* forms for the consent form(s) and recruitment materials must be uploaded to the eBridge SmartForm.

REFERENCES:

45 CFR 46.102(c)

45 CFR 46.116

21 CFR 50.3(1)

SUPPORTING DOCUMENTS:

IRB SOP: Informed Consent Process for Human Subject Research

IRB SOP: Informed Consent Document for Human Subject Research

IRB Form: Translator Declaration

IRB Form: Back-Translator Declaration

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