Ascension WI IRB Guidance

Use of Short Form Consent for Non-English Speaking Subjects

The Belmont Principle of Justice calls for "… fair procedures and outcomes in the selection of research subjects." Accordingly, federal regulations require the consent document to be presented in language that is understandable to the subject and in most situations, that informed consent be documented in writing.

Based on this, the IRB prohibits the exclusion of non-English speaking individuals from research protocols, unless there is a sufficient justification for the exclusion, and reasonable efforts must be made to accommodate non-English speaking individuals.

Options for Obtaining Consent from Subjects Who Do Not Speak English

Written translation of the IRB approved English consent document

If the study intendeds to enrolls non-English speaking subjects, the Investigator needs to plan for the inclusion of non-English speaking subjects.

Subjects who do not speak English should be presented with a consent document written in language understandable to them, meaning that the consent form is translated prior to identifying a possible subject. The WFH IRB strongly encourages use of this procedure whenever possible.

IRB approval is required prior to using a translated consent form and a certification of translation should be provided to the IRB when the non-English language consent form is submitted for review. The translated consent document can be submitted for IRB review as an amendment after the IRB approves the English language consent document (which should be used for translation).

Short form consent process

Alternatively, the IRB may permit an oral presentation of consent document information along with a "short form" consent document written in a language understandable to the subject.

The short form is an abbreviated written consent document that states that the elements of informed consent (required by federal regulation) were presented orally to the subject or the subject's legally authorized representative.

The short form consent process may only be used when:

- The Investigator is not targeting a non-English speaking population
- Only a few subjects are anticipated to speak the same non-English language

If more than an occasional subject speaking the same non-English language will be enrolled in a study, then a fully translated consent form is required.

Obtaining consent using the short form process

Investigators must obtain IRB approval before using the short form consent process.

Federal regulations (45 CFR 46.117(b)(2)) permits oral presentation of informed consent information in conjunction with a short form written consent document and a written summary of what is presented orally. The summary is usually the IRB approved English language consent document.

A witness is required to be present during the oral presentation. This witness must be fluent in both English and the language of the subject, and may not be a family member or friend of the subject. Typically, institutional translational services are utilized. When the person obtaining consent is assisted by a translator, the translator may serve as the witness.

Additionally, the subject must be given copies of the short form document and the summary.

Documenting short form consent process
Any institutional requirements for documentation of consent remain the same.

In additional requirements for the short form process include the following:

- the short form document should be signed by the subject or subject's legally authorized representative and the witness
- the summary should be signed by the person obtaining consent as authorized under the protocol and the witness

Getting IRB Approval to Use the Short Form Consent Process

When an Investigator identifies a possible subject who does not speak English and the study consent document has not already been translated to their language, the Investigator can request IRB approval to use the short form consent process.

This request should be submitted as an amendment through Mentor and include a justification and a description of any additional safeguards in place to ensure the protection of the rights welfare and safety of the subject throughout the study. This will vary by study, but may include approval from Interpreter Services to allow the use of an institution translator at every study visit.

Along with the amendment form, the Investigator must submit the short form in the language of the possible subject. The WFH IRB has the short form available in numerous languages, including Bosnian, Hmong, Russian and Spanish. These forms are available on the IRB Info page of Mentor. If a different language is needs, please contact the IRB office.

Once approved, the investigator may obtain consent following the process described above.

For additional information to about the short form consent process, see:

- SOP-901 Informed Consent for Research
- SOP-902 Documentation of Informed Consent
- SOP-909 Research Involving Subjects with Limited English Proficiency
- IRB Guidance: Research Informed Consent and HIPAA Authorizations/Waivers in the Medical Record
- OHRP Guidance

You may also contact IRB staff with questions.