Department	**Title**	**Dates**
Research Integrity and Protection	Research Involving Subjects with Limited English Proficiency	Effective: 10/25/2017
		Approved: 6/21/2017
Policy ID		Last Revised: n/a
IRB-SOP-909		Expiration: n/a

SOP

PURPOSE

This procedure explains and establishes the investigator and IRB responsibilities for ensuring additional protections are in place when involving subjects in research who may have limited English-proficiency. Federal Regulations (45 CFR 46.111(b), 21 CFR 56.111(b)) require IRBs give special consideration to protecting the welfare of particularly vulnerable subjects. The Ascension Wisconsin IRB considers adults with limited English proficiency to be a vulnerable population and must determine whether such participants should be recruited or whether additional safeguards are required to ensure the rights and welfare of subjects. This procedure outlines the investigator responsibilities when enrollment of non-English or limited-English proficient research subjects is unexpected or anticipated.

SCOPE

This SOP applies to all research conducted at Ascension Wisconsin that involves subjects who may have limited English proficiency, as possible human subjects. This SOP is in addition to the general requirements for obtaining and documenting informed consent outlined in *SOP: Informed Consent Process for Research* and *SOP: Documentation of Informed Consent for Research*.

DEFINITIONS

Consent: Consent refers to an agreement to participate in a certain action after thoughtful consideration.

Legally Authorized Representative (LAR): A person authorized either by statute or by court appointment to make decisions on behalf of another person. In human subject research, an individual, judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

PROCESS

1. **Inclusion of Subjects with Limited English Proficiency**
   - **1.1.** The inclusion of subjects in research who are not fluent in spoken or written English ensures that the burdens and benefits of research are justly distributed and that subject selection is equitable.
   - **1.2.** 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. The Investigator and IRB should consider the impact of excluding non-English speakers on the scientific validity and generalizability of the research.
   - **1.3.** Both the Investigator and the IRB should consider how likely it is that they will encounter subjects who do not speak English and how they will obtain consent from those individuals.

1.4. The process for obtaining consent and additional consideration and safeguards for subjects with limited English proficiency should be described in the protocol and IRB application, including information about the following:

- Investigators must assure that the limited or non-English speaking subjects fully understand their role in the study and provide voluntary informed consent.
- If appropriate, researchers should have an ongoing arrangement for an interpreter, to convey the subject's questions and concerns throughout the study. For example, a study involving an investigational drug may need to have an interpreter on call, should a subject have an urgent question or problem related to the drug**.**
- Investigators should describe how other study documents, such as questionnaires, instructions for using medical devices, brochures, etc., will be translated or communicated.

2. Consent Process and Translation

2.1. The consent presentation and discussion must occur in a language that is understandable to the subjects. This may require the researcher to provide translated documents and an interpreter who is qualified to adequately obtain consent and answer questions in a consistent and reliable manner.

2.1.1. The IRB application should describe who will serve as interpreter, and the nature of the qualifications. Typically, Ascension Wisconsin Translational Services must be used.

2.1.2. If the researcher anticipates identifying subjects who do not speak English, the consent forms must be translated by a certified translator and approved by the IRB before use.

2.1.2.1. A certified translation requires the following: English-language version of the document, foreign-language version of the document, back-translation of the document, and a signature of the person or company doing the translation that guarantees the accuracy of the translation. The IRB may also require documentation of the medical/scientific regulatory expertise of the translator.

2.1.3. When conducting the consent process, Investigators should ensure the following:

- Study team members conducting consent must be familiar with the study and fluent in both English and the subject's primary language, OR
- In addition to the study 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 translate questions and answers for the subject.
- Investigators should ensure that an individual who is familiar with the study and fluent in both languages is available by phone or in person to answer questions during the conduct of the study.

2.2. The IRB has the authority to require revisions or additions to the consent process to ensure that non-English speaking subjects are adequately informed and are providing truly voluntary consent.

3. Unexpected Enrollment of a Subject with Limited English Proficiency

3.1. If an investigator unexpectedly identifies an opportunity to enroll a subject with limited or no proficiency in English, federal regulations allow the use of a "short form" in a language the subject understands, instead of a translated consent form, in order to document that all required elements of informed consent were presented orally.

3.2. The Investigator must submit a request, in the form of an amendment, to use the short form process and the IRB must approve the process prior to use. Additionally, protocols that require reading or written responses from the subject, such as diaries and surveys, may be not appropriate under this procedure. Investigators should carefully consider and plan how these documents will be translated and made available to the subject.

3.3. 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.

4. Use of the short from process for studies that involve greater than minimal risk, including studies of an investigational drug or device

4.1. The short form consent process can be used to approach subjects and obtain consent for screening procedures to occur.

4.2. The complete study consent form must be translated, approved by the IRB and presented to the eligible subject prior to their continuation in research specific procedures.

4.3. In rare cases, the IRB may allow for and exception to use only the short form to enroll a subject into a greater that minimal risk study. The Investigator must obtain approval prior to enrollment and the IRB must determine that the justification and information provided by the Investigator warrants the exception and makes adequate provisions to safeguard the rights welfare and safety of the subject.

This exception may not be granted to enroll subjects whose native language is one of the Ascension Wisconsin safe harbor languages, as described in the Ascension Wisconsin Policy on Vital Documents. In these cases, 4.1. and 4.2. above must be followed.

5. Obtaining Consent Using the Short Form process

5.1. A short form written consent document in the subject's primary language must be presented as well as study specific information presented orally, which is typically presented using the English language consent form.

5.2. 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.

5.3. In addition to the general requirements for documentation of consent, the short form process includes 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

5.4. A written copy of the short form and the summary of what is presented orally must be provided to the subject.

REFERNCES

45 CFR 46.116, 45 CFR 46.117
21 CFR 50.20, 21 CFR 50.27
FDA Information Sheet: "A Guide to Informed Consent"
FDA Information Sheet: "Institutional Review Boards Frequently Asked Questions"

RELATED MATERIAL

IRB Templates: Short Form documents

REVISION HISTORY

Version #	Date Revised	Reason for/Brief Description of Change	Revised By
01	6/21/2017	New- Initial Integration Update	J. Blundon