Non-English Speaking – Study Requirements

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1.0 Purpose
To aid in assuring knowledge and compliance of all persons involved in any aspect of human subject research by documenting the processes for the review and implementation of studies that include participants who primarily speak a language other than English. This is to ensure that non-English speaking subjects are properly consented per 45 CFR 46.116 and 21 CFR 50.20.

2.0 Scope
The SOP applies to all human subject research falling under the purview of the Health Sciences Institutional Review Board.

3.0 Policy/Procedure
Translation and Interpretation

Translation is the process of translating a written document (e.g., consent form) from one language into another, assuring the language of the translated document has the same meaning as the written document in the first language.

If a study specifically includes a non-English speaking population, translated and back translated versions of all documents that would be disseminated to the population need to be submitted for review unless otherwise justified and approved by the board. Federal regulations require that informed consent information be presented "in language understandable to the subject" (45 CFR §46.116 and 21 CFR §50.20).

Professional translation of the complete consent/assent form(s) is required unless the IRB has granted approval for the use of a short form. The translated consent and assent forms must be stamped as approved by the IRB prior to use.

The HSIRB must have all final versions of all non-English documents and their English equivalents, at the time of review for any study targeting non-English speaking subjects. If the Principal Investigator decides to include Non-English speaking populations after original study approval, non-English and English versions of appropriate documents must be submitted through the amendment process.

The following documents should be translated and back translated for review by the board:

1. The Informed consent/assent document(s)*
2. The Authorization for the Use of Personal Health Information for Research (when applicable)
3. Any study related documents that will be given or seen by the participants such as surveys and advertisements

*See the HS IRB Policy – Informed Consent Types and Elements for the requirements of the informed consent document.

An interpretation is a verbal exchange between the subject (or their representative) and an investigator (or other member of the study team authorized to obtain consent), which is facilitated by an interpreter who is fluent (can speak and read) in English and the language of the subject. If applicable, the interpreter should have an understanding of healthcare.

Interpreters are generally considered as providing a for-hire service and are not involved in the conduct of the research and therefore do not need to be added to the IRB application. Study staff must not rely upon the subject’s family or friends as the interpreter. An interpreter must be available to non-English speaking subjects when the subjects may have questions or concerns. This availability must coincide with the availability of the counterpart English-speaking study staff.

The translator’s and interpreters qualifications (CV and any certifications) must be forwarded to the HS IRB office as documentation of qualifications.
Unexpected Encounter with non-English speaking subject

On occasion, a subject may come forward who speaks a language other than the targeted populations, and so no translated consent may presently exist for the subject. In this event that study documents were written in a language other than the language used by the new potential subject, an interpreter may be used in conjunction with the short form.

Studies should consider all populations that may be targeted so that unexpected encounters are minimized.

If additional subjects may be encountered who use this non-English language, the Principal Investigator should proceed to create documents in the new language through an amendment.

**Short Form Process and Requirements** *(45CFR §46.117 (b)2 and 21 CFR 50.27(b)2 for FDA regulated studies)*

When this method is used, a witness that is fluent in both languages is required for the consent process.

An HS IRB approved written summary of what is to be said to the subject or the representative is presented to the subject or the subject’s legally authorized representative.

An HSIRB approved short form written consent document stating that the elements of informed consent required by *(45CFR 46.116 and 21CFR 50.25)* has been presented orally to the subject (or the subject's legally authorized representative) is required.

The short form itself is signed and dated by the subject or the representative.

The witness signs and dates **both** the short form and a copy of the summary of what is said.

The person actually obtaining consent signs and dates a copy of the summary of what is said.

A copy of the summary and the short form is given to the subject or the representative.

The primary investigator retains the original signed and dated short form and summary.