University of Wisconsin-Oshkosh
Institutional Review Board (IRB)

STANDARD OPERATING PROCEDURES (SOP)	
SOP Number: 4 Effective Date: May 4, 2016 Review Dates: July 16, 2019, May 17, 2023 Last Reviewed: May 17, 2023 Attachment: Page 1 of 7 Prepared and Revised By: K. Schill, L. Mann, A. Miron & M. Bublitz	**Title:** **Non-English Speaking Participants**

Non-English Speaking Participants

Purpose:

This procedure will aid the IRB in documenting the process for the review and implementation of studies that include subjects who primarily speak a language other than English. This procedure will assist researchers who wish to enroll non-English speaking participants with IRB requirements for:

- Obtaining informed consent
- Translation of informed consent and related study materials
- Selection and use of translators and interpreters

Policy:

The IRB must ensure that non-English speaking participants are properly consented per the federal HHS regulations for obtaining legally effective consent, 45 CFR 46.116, as outlined in ***SOP # 3 Informed Consent Process***. Guidance from OHRP on *Informed Consent of Subjects Who Do Not Speak English* was referenced in the development of this standard operating procedures form.

The researcher is responsible for ensuring that all study information and documents will be provided to participants "in a language understandable to them". The governing principles of human subject research entail that researchers should not exclude subjects based solely on their inability to read, speak or understand English. Investigators need to be able to communicate directly with subjects, or to provide a reliable alternative to ensure that:

- Study participation is voluntary, as indicated by free and truly informed consent; and
- Study information, procedures, benefits, and risks are accurately communicated, and subjects have ongoing opportunities to express concerns and ask questions, in order to minimize risks to subjects; and
- There are fair procedures and outcomes in the selection of research subjects so that risks and benefits of research are shared in society.

Definitions:

Translation: the rendering of a source language text in to the target language so as to ensure that (1) the surface meaning of the two will be approximately similar and (2) the structures of the source language will be preserved as closely as possible.

(Note: Structure of the source language will be preserved as closely as possible during translation but not so closely that the target language structures will be seriously distorted.)

A) Interlingual Translation: replacing a word with another word belonging to a different language
B) Intralingual Translation: a word belonging to a particular language is replaced by another word belonging to the same language
C) Intersemiotic Translation: more than focusing on words, emphasis is on the overall message that needs to be conveyed (Ex: sign language)

Back Translation: refers to the practice of translating materials from one language to another language and then (in a separate action) translating the materials back into the original language. The purpose is to evaluate the quality and integrity of the translation.

Interpreter: refers to a person who reads aloud (in another language) materials written in English, or who conveys (in another language) information that is spoken in English.

Legally Authorized Representative (LAR): a person authorized by statute or court appointment to make decisions on behalf of another, in this case, on behalf of the participant; or one or both biological or adoptive parents when the participant is a minor. The LAR is not considered a participant of the study. Under the New Rule, the definition of legally authorized representative now adds specific authorization to use institutional policy when there is no applicable law (state statute or regulation, case law, or an opinion of a state attorney general) that addresses this issue. When there is not an applicable law, this change allows policies that are in place in a non-research context (for example, clinical context) to be used to determine who may serve as a legally authorized representative at an institution.

Procedures:

I. Procedure for Obtaining and Documenting Informed Consent:

There are two methods for obtaining and documenting informed consent for research subjects who do not read, speak, or understand English. It is the responsibility of the IRB to determine which of the procedures at §46.117(b) is appropriate for documenting informed consent in protocols that it reviews.

Methods:

A. Method 1: The **preferred method** is to provide consent forms and study documents written in the subject's language (45 CFR 46.117 (b)(1)).
B. Method 2: For the occasional and unanticipated non-English-speaking subject, an alternative "**short form" method** is allowed (45 CFR 46.117(b)(2)).

1. **Method 1: Preferred Method for Obtaining Informed Consent from Non-English Speaking Participants:**
   - Where informed consent is documented in accordance with 46.117 (b)(1), the written consent document should embody all required elements necessary for legally effective informed consent. See ***SOP #3: Informed Consent Process***.
   - OHRP strongly encourages investigators to provide a written consent document in a language understandable to the subject whenever possible.
   - If the investigator anticipates a substantial portion of eligible subjects to be non-English speaking people, study documents and translated consent forms in the common languages should be prepared in advance.

2. **Method 2: Alternative Short Form Method for Obtaining Informed Consent from Non-English Speaking Participants:**

- Alternatively, §46.117(b)(2) permits oral presentation of informed consent information in conjunction with a short form written consent document (stating that the elements of consent have been presented orally) and a written summary of what is presented orally. A witness to the oral presentation is required, and the subject must be given copies of the short form document and the summary.
- The alternative "short form" method for obtaining informed consent should only be used for the occasional and unexpected enrollment of a non-English-speaking subject in a study for which no consent form in the subject's language has been prepared.

Procedure for the Alternative Short Form Consent Method:

1) The investigator can request a short form consent process for the IRB to consider.
2) The short form consent template (see the end of this document for an example) has been updated to comply with the Revised Common Rule. All study teams who plan to use a short form must follow the updated instructions found here. You must submit the English and translated short form along with a certificate of translation to the IRB for approval.
3) The IRB must receive all foreign language versions of the short form document as a condition of approval under the provisions of §46.117(b)(2). Expedited review of these versions is acceptable if the protocol, the full English language informed consent document, and the English version of the short form document have already been approved by the convened IRB.
4) The PI should file the original signed and dated approved IRB full English version consent form with the original signed and dated short form consent in the ***participant's*** research record.
5) Considerations regarding interpreters and witnesses:
   a) An interpreter must assist with the consent process. As with any consent process, only study team members approved to participate in the consent process as a consent designee should be involved in reviewing the approved full English version of the consent form with participants. The interpreter will listen to the information presented in English by the study team member and communicate the information to the participant in his or her own language. The consent process must be witnessed by someone who is fluent in both English and the participant's language and must be unaffiliated with the study.
   b) The witness may also be the interpreter (unless the interpreter is affiliated with the study as an investigator or study team member), per OHRP guidance: *Informed Consent of Subjects Who Do Not Speak English*.
   c) If a member of the research team is fluent in English and the language of the potential participant, they may serve as the translator and the person obtaining consent but would need an impartial witness present if using the short form method.

6) Considerations regarding the consent process:
   - Study ***participant*** must sign the short form consent in his/her chosen language and be allowed an opportunity to have any questions answered.
   - ***Interpreter/Witness*** must sign the short form consent and the approved IRB full English version of the consent form. The witness must be present

during the oral presentation of the English version of the IRB-approved consent document. The witness must be fluent in both languages.

- ***Consent designee*** or Legally Authorized Representative (LAR) must sign the approved full English version consent form.
- Study ***participant*** must get a copy of the signed and dated short form consent and a copy of the signed and dated approved IRB full English version consent form (signed by the witness and consent designee).

II. Procedure for Translation or Interpretation of IRB Informed Consent and Study Materials:

When research is likely to involve subjects who are not fluent in English, a qualified translator/interpreter must be able to ensure that the tone, meaning, and content of the translated documents remain consistent with the IRB approved English version:

- Documents should be linguistically accurate
- Reading level must be appropriate for subject population
- Consent and documents should be culturally sensitive for the locale in which it will be used

The following documents should be translated before enrolling non-English speaking subjects on a study:

- The IRB-approved English Informed Consent/Assent document(s)
- HIPAA documents (when applicable)
- Any other approved document(s) as applicable (e.g. recruitment materials, survey, etc).

The researcher is responsible for ensuring that all materials will be provided to participants in a language understandable to them and for ensuring that translations and interpretations will accurately convey the information.

A. Procedure for Translation of Informed Consent Document and Study Materials:
   1. When completing the IRB Application, the PI should select Non-English Speaking (Application: Part III. Participants) if non-English speaking participants are expected to be included in the participant pool.
   2. A supplemental IRB Form titled, **Non-English Speaking Participants Form** must also be completed at the time of IRB Application submission for IRB Review. This will inform the IRB how the PI will ensure that translation requirements are met. This form will request the PI to provide the background, experience, and language proficiency of the translator or interpreter.
   3. The IRB will review the IRB Application and supplemental **Non-English Speaking Participants Form** and must approve the English Version of the Informed Consent Document and study materials prior to the PI submitting the translated documents.
   4. Once the Informed Consent Document and any supplemental materials have been approved by the IRB in English, the PI may submit a **Modification Request Form** to the IRB for approval of the translated materials. The modification form will also prompt the researcher to submit a document from the translation service, translator, or interpreter describing their background, experience, and qualifications for completing the translation.
   5. The IRB must review and approve the modification request and translated materials before enrollment of the Non-English Speaking Subjects can begin.
   6. If the PI or research personnel will be assisting in obtaining consent from participants not fluent in English, the IRB may request additional training for research staff in the cultural norms for the population.

7. If during the course of a study, the PI unexpectedly encounters a participant that does not speak or read English, they may submit a modification request to the IRB for obtaining informed consent in the participant's language (method 1, part I.A) or using the alternate short form method (method 2, part I.B) as described above.

III. Translation Requirements for Greater than Minimal Risk Studies:

A. Approved methods when the IRB determines that the research is greater than minimal risk:

1. Method 1:
Certified translation services is the preferred method for greater than minimal risk studies (as determined by the IRB). A certified translation is one that has been formally verified by a licensed translator or translation company for use in official purposes. Certified translators attest that the target-language text is an accurate and complete translation of the source-language text. Certified translation of consent documents ensures that the tone, meaning and content of the translated documents remain consistent with the IRB-approved English version. The IRB does not require a researcher to use a specific translation service or endorse any specific translation service. The American Translators Association maintains a directory for: 1) translation and interpreting services by Individuals, and 2) translation and interpretation companies.

2. Method 2: The IRB may consider translation by a qualified individual fluent in English and the language to be translated. A back translation would also be required by another separate individual that has no relationship to the original translator to ensure the meaning, tone, and content of the documents are consistent with the IRB-approved English Version. Native speakers who have demonstrated proficiency in English may serve as sources of translation, including knowledgeable members of the research team or faculty or instructors of foreign language programs at UW Oshkosh or another academic institution A letter from the translator describing their qualifications must be provided with the translation documents.

The researcher is responsible for the cost of translating documents. When possible, these costs should be written into contracts or grants.

IV. Translation Requirements for Minimal Risk Studies:

Studies that are eligible for expedited review, involving minimal risk, also require translation of the consent/assent forms and study documents; however, certified translation or an independent back translation is not required. The IRB will accept documents translated by an individual fluent (i.e., can speak, read and write) in a given language. Native speakers who have demonstrated proficiency in English may serve as sources of translation, including knowledgeable members of the research team or faculty or instructors of foreign language programs at UW Oshkosh or another academic institution. UW Oshkosh Foreign Languages Department holds a list of faculty and staff members who are fluent in languages other than English. The qualifications of the individual performing the translation will be assessed by the IRB. A letter from the translator describing their background and qualifications must be provided with the translation documents.

V. IRB Review and Approval of Translated Documents:

It is unlikely that the IRB will have members proficient in many of the languages that are presented to the IRB for review. Therefore, the IRB's review will focus on the whether the translation method is appropriate for the study based on:

- Translator's/interpreter's background, experience, and language proficiency
- Local cultural context and issues

- Risks to subjects

The IRB may invite ad hoc consultants to assist in the review of translated documents and to explain the cultural context of documents, however ad hoc consultants cannot vote on IRB business.

VI. IRB Review and Approval of Translator/Interpreter Selected:

The IRB will review the supplemental **Non-English Speaking Participants Form** to determine whether the selection of the translator/interpreter is appropriate. The researcher is responsible for ensuring that all materials are provided to participants in a language understandable to them.

- The IRB recommends that the translation/interpretation be performed by someone who holds no relationship to the participant.
- Privacy, confidentiality, and accuracy of translation/interpretation should be considered if family members or friends are asked to be translators/interpreters.
- If a member of the research team speaks the participants' language, they may act as the interpreter and the person obtaining consent if the IRB approves of the method. (Note: A member of the research team acting as interpreter *and* person obtaining consent *cannot* also act as witness when using short form consent method as described in Part I.B.2.).
- Children are usually not appropriate interpreters, except in rare situations where children are considered adults in the local setting, the risks are low, there are no alternatives, and there are no potential conflicts of interest.
- If the research involves a medical procedure, a trained medical translator should be used

References:

Code of Federal Regulations on Human Subjects Research. http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html. Accessed on 3/28/2023.

Office of Human Research Protections (OHRP) Guidance: *Informed Consent of Subjects Who Do Not Speak English* (1995) http://www.hhs.gov/ohrp/policy/ic-non-e.html Accessed on 3/28/2023

University of Washington Human Subjects Division, "Translation and Interpretation SOP." https://www.washington.edu/research/wp-content/uploads/TIPSHEET_Consent_v1.2_2022.12.29.pdf Accessed on 3/28/2023

University of Missouri-Columbia, "Non-English Speaking Study Requirements SOP." https://docs.research.missouri.edu/human_subjects/SOP_Additional_Protections_for_Vulnerable_Populations,_International,_and_Non_English.pdf Accessed on 3/28/2023

John Hopkins University IRB, "Informed Consent Document for Research Participants Who Do Not Speak English (Short Form)"; https://www.hopkinsmedicine.org/institutional_review_board/forms/short_form_translation.html, Accessed on 3/28/2023

Principal Investigator:_____
Application No.:_____
Study Title: _____

Consent to Participate in Research (Short Form)

You are being asked to participate in a research study. Before you agree, you must first be provided with a summary of the research study. This summary must contain the key information to help you understand the reasons why you might or might not want to join the study.

After presenting the summary, the study team will provide you with additional details about the study which must include:

(i) the purposes, procedures, and duration of the research;
(ii) any procedures which are experimental;
(iii) any reasonably foreseeable risks, discomforts, and benefits of the research;
(iv) any potentially beneficial alternative procedures or treatments; and
(v) how confidentiality will be maintained.

Where applicable, the study team must also tell you about:

(i) any available compensation or medical treatment if injury occurs;
(ii) the possibility of unforeseeable risks;
(iii) circumstances when the investigator may halt your participation;
(iv) any added costs to you;
(v) what happens if you decide to stop participating;
(vi) when you will be told about new findings which may affect your willingness to participate; and how many people will be in the study.
(vii) For clinical trials: A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

If you agree to participate, you must be given a signed copy of this document and a written summary of the research.

You may contact *(name)*_____ at *(phone number)* _____ any time you have questions about the research.

You may contact *(name)*_____ at *(phone number)* _____ if you have questions about your rights as a research subject or what to do if you are injured.

Your participation in this research is voluntary, and you will not be penalized or lose benefits if you refuse to participate or decide to stop.

Signing this document means that the research study, including the above information, has been described to you orally, and that you voluntarily agree to participate.

_____ _____
Signature of participant Date/Time

_____ _____
Signature of interpreter/witness Date/Time