	<b>IRB SOP: Recruitment &amp; Enrollment of Non-English Proficient or Limited -English Proficient Subjects</b>		
	NUMBER	APPROVED BY	EFFECTIVE DATE
	HSR-630	Miranda van Tilburg, PhD IRB Chair, IRB Office Campbell University	12/02/2020

**Applies to** Campbell faculty, faculty advisors, students and staff conducting or overseeing human subjects research.

## Purpose

This procedure outlines the Investigator responsibilities when recruitment and enrollment of non-English or limited-English proficient research subjects is unexpected or anticipated.

## Background

The IRB supports Investigators in expanding access of research protocols to subjects with limited or non-English proficiency. 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. They may also be included because the area of research necessitates involving limited or non-English proficient subjects, for example international projects. Investigators must assure that the limited or non-English speaking subjects fully understand their role in the project and provide voluntary informed consent.

## Definitions

**Consent:** refers to an explicit agreement to participate in a certain action, particularly and especially after thoughtful consideration.

**LEP:** Limited-English proficient.


**NEP:** Non-English proficient.

**Legally Authorized Representative (LAR):** “An individual or 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.” (45 CFR 46.102 (c)) (21 CFR 50.3(1))

## Investigator Responsibilities and Procedures

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

1. When project is anticipated to recruit and enroll LEP or NEP subjects, the Principal Investigator (PI) must identify in the *New Protocol Submission Form and Research Plan* the target populations, the language(s) and must specify who will provide the translation and interpretation and their qualifications. In addition, the *Research Plan* 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 process detailed in *IRB SOP: Informed Consent Process for Human Subjects 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 *New Protocol Electronic Application Form*.

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- d. If the Translator's Declaration and Back-Translator's Declaration apply, these must be completed, signed, and uploaded with the submission, for the consent form(s) and recruitment materials and all other subject documents, which they are to complete.

#### **For Projects enrolling only non-English Speaking subjects**

1. The Investigator must provide the proposed consent form and other documents in English and in the language of the subjects.
2. The Investigator must provide the Back-Translator's Declaration for the consent form(s) and recruitment materials and all other subject documents, which they are to complete.

#### Informed consent process


- Investigators must provide a consent form in a language understandable to the subject. The consent form must follow the appropriate *CU IRB Informed Consent Document for Human Subjects Research template*. Both the translated consent form, the back translation and the English version must be reviewed and approved by the IRB before use.
- When conducting the consent process, Investigators should ensure:
  - Project team members conducting consent must be familiar with the project and fluent in both English and the subject's primary language, OR
  - 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 or someone else who could have undue influence, e.g., a teacher in a course) and who will be present to translate questions and answers for the subject.
- 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

- 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.
- Investigators must describe the process for administering the questionnaire or survey in the *Research Plan*.

#### Projects conducted in the community at large

- The following qualifications must be observed when identifying who can serve as an interpreter for a project:
  - No minor under the age of 18 can serve as an interpreter.
  - Family members cannot serve as the interpreter
  - Anyone who can have undue influence on participation, such as a teacher in a course, cannot serve as the interpreter

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- If selecting an interpreter from the community from which subjects will be recruited, a plan to ensure confidentiality must be described in the *Research Plan*.
- 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 native speaker who holds the equivalent of a high school education
  - An individual who holds a degree in the language of the target population(s)
  - A certified or credentialed translator.
- 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. The translation and back-translation cannot be performed by the same individual.
- 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 *New Protocol Electronic Application Form*.

## References

45 CFR 46.102(c)

45 CFR 46.116

*IRB SOP: Informed Consent Process for Human Subjects Research*