

# Obtaining Consent from Non-English-Speaking Persons (HRPP 5.7)

## **Description:**

This policy describes UNMC's requirements for the process and documentation of informed consent for non-English speaking persons.

## **Definitions:**

**Qualified Interpreter:** must be fluent in English and the subject's language and preferably has a basic understanding of the medical or other scientific terminology related to the research.

## **Specific Protections and Requirements for Non-English Speaking Subjects:**

### **Subjects:**

#### **Expected Enrollment of Non-English-Speaking Subjects:**

If the study is expected to include a significant number of non-English speakers, the following is required:

- Translated consent forms, prepared by a **Qualified Translator** (see *Addendum A*)
- **Qualified Interpreter** must be identified in advance (see *Addendum B*)
- Interpreters must be given the IRB-approved ICF ahead of time whenever possible
- The subject and interpreter must sign and date the non-English ICF at the conclusion of the consent process
- The person obtaining consent must sign and date the English version of the ICF
- The consent process must be documented in the medical or research record, including:
  - Names of those involved in the consent process
  - Interpreter's name or other identifying information (such as employee number)

## **Unexpected Enrollment of a Non-English-Speaking Subject:**

If there is an unexpected opportunity to enroll a non-English speaking subject and a consent form translated into the appropriate language is not available:

- **Scenario A: No Direct Therapeutic Benefit**

- Person may be enrolled if:
  - IRB has reviewed and approved a translated ICF, and
  - An interpreter is used during the consent process

**NOTE:** the PI or other study personnel may serve as the interpreter

- **Scenario B: Prospect of Direct Therapeutic Benefit**

- Subject may be enrolled using the IRB-approved short form, following [HRPP Policy 5.5](#)

## **ADDENDUM A**

**NOTE:** this is a summary of the full policy, which can be found [here](#).

### **Minimal Requirements for Translation of Informed Consent Documents**

#### **General Criteria:**

- Translators must be fluent in English and the language of translation
- Preferably, translators should have knowledge of research methodology

#### **For Research Conducted Solely Within the Organization:**

Acceptable translation methods (*in order of preference*):

- 1) American Translators Association (ATA) certified translator
- 2) Translator certified by another non-profit organization, or Federal, State or Municipal government agency
- 3) Professional translation service (must certify accuracy)
- 4) “Competent to translate” individual
  - a. Must include certification statement affirming translation is complete and accurate

**b. Qualifying individuals:**

- i. Foreign language instructors (university/college)
- ii. Graduate language students (currently enrolled)
- iii. Bilingual individuals (including research staff) fluent in both languages

- c. For greater than minimal risk research: back-translation is required by a different person/group, preferably from categories 1-3
- d. For multi-institution research where the Organization is a participating site, translation must be accompanied by documentation that the translation was performed by a “qualified” individual, as defined above

## **ADDENDUM B**

**NOTE:** this is a summary of the full policy, which can be found [here](#).

### **Minimal Requirements for Interpretation:**

#### **General Requirements:**

- Interpreters must be fluent in English and the subject’s language
- Preferably with research methodology knowledge

#### **Qualified Interpreters (*in order of preference*):**

- 1) Certified Interpreter through the National Board of Certification for Medical Interpreters, Certification Commission for Healthcare Interpreters, or any similar credentialing body, or certified by any other non-profit organization, or Federal, State or Municipal government agency
- 2) Organization-employed/contracted interpreter
  - a. Includes clinical context providers and commercial services (e.g. CyraCom)
- 3) UNMC, NM, Children’s, BMC, UNO, or study site staff who are fluent in both languages
- 4) Study personnel fluent in both languages
- 5) Other fluent individuals that preferably understand research context including:
  - a. University language instructors
  - b. Graduate language students
  - c. Other bilingual persons

#### **Additional Considerations:**

- If a subject/LAR wishes to bring their own interpreter, a Qualified Interpreter (as described above) must still be present to ensure accuracy
- **Minors may NOT serve as interpreters under any circumstance**