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: an individual fluent in English and in the spoken language of the subject, and preferably who has a basic understanding of the medical or other scientific terminology related to the research.

Non-English-Speaking Subjects:

- If it is reasonable to expect a significant number of non-English speaking subjects, the IRB may require a translated consent form.
  - Consent forms must be prepared by a qualified translator.
  - A qualified interpreter must be identified.
  - The subject and interpreter must sign and date the non-English version of the consent form.
    - If the interpreter is not present during the consent process, they may utilize the remote consent process (HRPP Policy 5.3).
  - The person obtaining consent signs and dates the English version of the consent form.
- 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:
  - If the research offers NO direct therapeutic benefit, the person may be enrolled if:
    - The IRB reviews and approves a translated consent form.
    - An interpreter is used during the consent process.
      - The PI or other study personnel may serve as the interpreter.
  - If the research DOES offer direct therapeutic benefit, the person may be enrolled using the IRB-approved short form (HRPP Policy 5.5).
Minimal Requirements for Translating Informed Consent Documents:

- Must be performed by qualified persons, with adequate competence in English and the language of translation.
- Acceptable translation by a “qualified” translator includes, in order of preference:
  - Translation provided by a translator certified by The American Translators Association
  - Translation provided by a translator certified by any other non-profit organization or Federal, State, or Municipal government agency.
  - Translation accompanied by a certification statement. A person deemed “competent to translate” includes:
    - Foreign language instructors employed by an accredited University/college
    - Graduate students in a foreign language currently in training at an accredited University/college
    - Bilingual person able to write fluently in 2 languages (MAY be a member of the research team)
    - For research greater than minimal risk, translation accompanied by a certification statement must be accompanied by a back-translation by a different person or group.

For multi-site research where another IRB is the IRB of record, a translation must be accompanied by documentation that the translation was performed by a “qualified” individual (as defined above).

Minimal Requirements for Interpretation:

- Must be performed by a qualified person, fluent in both English and the language of the subject.
- “Qualified” interpreters, in order of preference:
  - Person holding certification by:
    - National Board of Certification for Medical Interpreters
    - Certification Commission for Healthcare Interpreters
    - Similar credentialing body
    - Other non-profit organization
    - Federal, State, or Municipal government agency
  - Person employed by/contracted by the Organization to provide interpretation services in a clinical context (includes commercial interpretation services).
  - UNMC, NM, CHMC, BMC, UNO, or study site staff who are fluent in both English and the language of the subject.
  - Other persons, including:
    - Foreign language instructors employed by an accredited University/college.
    - Graduate students in a foreign language currently training at an accredited University/college.
- Bilingual person
- Prospective subjects may designate their own interpreter, but a Qualified Interpreter (from the above list) must also be present.
- A minor cannot be an interpreter.