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 from.
        - 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.