Short Form Consent (HRPP 5.5)

Description:

This policy describes UNMC's requirements for use of a short form written consent document for enrollment in research.

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

Permitted Under the Following Conditions:

- A subject/LAR who cannot understand English is **unexpected encountered**
- There **isn't sufficient time** to create and obtain IRB approval for a fully translated ICF, and
- The research **offers direct therapeutic benefit** to the subject

Key Restrictions:

- NOT a substitute when non-English speakers are expected: the IRB may require a fully translated ICF
- **Enrollment limit: no more than 3 subjects per language,** per protocol
    - More than 3 = fully translated ICF required
- Short form use with external IRBs is allowed only if approved by the IRB of record

Applying for a Short Form:

1) **Submit a short form request via RSS:** must be approved by the IRB Executive Chair/designee
2) Approval is:
    a. **Valid for 2 weeks**
    b. **Valid for 1 subject only**
    c. Extensions require justification
3) If an IRB-approved short form is not available in the language requested, the investigator may develop one based upon the IRB-approved English version; this must be approved by the IRB before use:

Short Form Consent Process:

Qualified Interpreter:

- **Required:** a Qualified Interpreter fluent in English and the subject/LAR's language
- If the subject/LAR/parent designates their own interpreter:
    - A Qualified Interpreter must still be present to ensure accuracy
    - This must be documented
    - A minor may NOT serve as interpreter

Interpreter's Role During Consent:

- Give subject/LAR a copy of the short form
- Person obtaining consent explains use of the short form with assistance from the interpreter
- The person obtaining consent with the help of the interpreter must:
    - Provide a concise explanation of key information
    - Describe the research and subject's rights
- The IRB-approved English ICF serves as the required summary
- Interpreter should be given the short form and the English ICF before the consent process if possible

Witness Requirements:

- A witness must be fluent in both English and the subject/LAR's language
- Must meet the same qualifications as the interpreter
- The Qualified Interpreter can serve as the witness, but study staff may not

Signature Requirements:

- Subject/LAR must sign and date the short form
- Person obtaining consent signs and dates the English ICF
- Witness signs both the short form and English ICF

Document Delivery:

- Provide the subject/LAR with copies of both signed documents
    - Signed short form
    - Signed English ICF

Other Considerations:

- The IRB may decide that the full ICF must be translated and provided to the subject as soon as possible after enrollment

Documentation:

- The following must be documented during the process of consent:
    - Names of individuals involved in the process of consent
    - Names and contact information of the interpreter and the witness

Minors:

- Short form must be signed by the parent/guardian of the minor
- No requirement for a study information sheet
- Minors must provide assent as follows:
    - **Ages 13+:** must sign the short form
    - **Ages 7-12:** must be verbally assented, with documentation in the record