

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: 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.

General Requirements:

- Use of a short form written consent document is **allowed when:**
 - A subject/LAR who cannot understand English is **unexpectedly encountered**.
 - **There isn't sufficient time** to develop and obtain IRB approval for a complete translated consent form.
 - Research presents the **prospect of direct therapeutic benefit**.
- Restricted to enrollment of **no more than 3 subjects per language** in any given protocol.
 - To enroll more than 3, a fully translated consent form is required.
- Permitted for clinical trials when an external IRB is the IRB of record if the IRB of record approves.

Process:

- Investigator completes a Short Form Request in RSS that must be approved by the IRB prior to using it.
- The **approval is valid for 2 WEEKS and may be used for 1 SUBJECT only**.
 - The approval period can be extended by the Executive Chair.

- 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 (which must be approved by the IRB before use).
- A **Qualified Interpreter** fluent in both English and the language of the subject/LAR must be identified.
 - If a subject/LAR/parent wishes to be their own interpreter, a Qualified Interpreter must also be present.
 - A minor cannot be an interpreter.
- The interpreter must be involved in the process of consent as follows:
 - A subject/LAR is given a copy of the short form.
 - The 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 complete ICF will serve as a summary.
 - Interpreters should be provided a copy of the short form and English version of the ICF.
- The following forms must be signed as follows:
 - The subject/LAR must sign and date the short form.
 - The person obtaining consent must sign and date the English version of the ICF.
 - The witness must sign both the short form and the English version of the ICF.
- A copy of the signed and dated short form and English version of the ICF must be provided to the subject/LAR.
- The IRB may decide that the full ICF must be translated and provided to the subject as soon as possible after enrollment.
- 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.
- Enrollment of a minor is permitted using the short form signed by the minor's parent/guardian.
 - Minors 13-18 must also sign the short form.
 - Minors 7-12 must give verbal assent that is documented.