

Obtaining Consent from Persons with Additional Needs (HRPP 5.7)

Description:

This policy describes UNMC's requirements for the process and documentation of informed consent for non-English speaking persons, or persons with additional needs or vulnerabilities participating in human subject research.

Visually Impaired or Blind Subjects:

- If it's reasonable to expect a significant number of blind or visually impaired subjects, the PI must provide a plan to assure the consent process includes necessary accommodations
- **Acceptable accommodations may include:**
 - Large font
 - Audio version of the consent form
 - Braille consent form
 - **May require:**
 - Transcription into print text, or
 - Review by a qualified Braille reader to confirm accuracy
 - Other assistive technologies
- If there is an unexpected enrollment of a blind or visually impaired subject, the IRB Executive Chair/designee may authorize use of any of the above methods

Signature Requirements:

- If possible, the subject should sign or make an "X" to indicate consent
- A witness not affiliated with the research must:
 - Observe the process
 - Witness the signature or mark
 - Sign the consent form, affirming that the subject received and understood the information

Hearing Impaired or Deaf Subjects:

- If it's reasonable to expect a significant number of deaf or hearing impaired subjects, the PI must provide a plan to assure the consent process includes necessary accommodations
- **Acceptable accommodations may include:**
 - American Sign Language (ASL) interpreter
 - Assistive communication technologies
- If there is an unexpected enrollment of a deaf or hearing impaired subject, the IRB Executive Chair/designee may authorize use of any of the above methods

Illiterate or Low Literacy Subjects:

- If it's reasonable to expect a significant number of illiterate or low literacy subjects, the PI must provide a plan to assure the consent process includes necessary accommodations
- **Acceptable accommodations may include:**
 - Reading the consent form aloud
 - Audio-recorded version of the consent form
 - Other technology
- If there is an unexpected enrollment of an illiterate or low literacy subject, the IRB Executive Chair/designee may authorize use of any of the above methods

Signature Requirements:

- Subject should sign or make an "X" to indicate consent
- A witness not affiliated with the research must:
 - Observe the process
 - Witness the signature or mark
 - Sign the consent form attesting that:
 - Information was accurately explained
 - Information was apparently understood
 - Consent was given freely