



## **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