

# 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 investigator must describe a plan to assure the consent process includes necessary accommodations which may include the following:
  - **Large font**
  - **Audio version of the consent form**
  - **Braille consent form**
    - If braille is utilized, the IRB may require a transcript or review by a qualified person who reads braille.
  - **Other technology**
- If there is an unexpected enrollment of a blind or visually impaired subject, the IRB Executive Chair may authorize use of any of the above methods.

If possible, the subject should sign (or make an "x") to signify consent.

- A witness unaffiliated with the research team must observe the consent process.
- The witness must sign the consent form.

## Hearing Impaired or Deaf Subjects:

- If it's reasonable to expect a significant number of deaf or hearing-impaired subjects, the investigator must describe a plan to assure the consent process includes necessary accommodations which may include the following:
  - **ASL interpreter**
  - **Appropriate assistive technologies**
- If there is an unexpected enrollment of a deaf or hearing-impaired subject, the IRB Executive Chair 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 investigator must describe a plan to assure the consent process includes necessary accommodations which may include the following:
  - **Reading the ICF to the subject**
  - **Use of a pre-recorded audio version of the consent form**
  - **Other technology**
- If there is an unexpected enrollment of an illiterate or low literacy subject, the IRB Executive Chair may authorize use of any of the above methods.

If possible, the subject should sign (or make an "x") to signify consent.

- A witness unaffiliated with the research team must observe the consent process.
- The witness must sign the consent form.