



Vulnerable Populations (HRPP 4.1)

Description:

This policy describes UNMC's requirements for additional protections for vulnerable populations.

Definitions:

Vulnerable Persons: individuals or groups who may have diminished autonomy or difficulty providing voluntary, informed consent due to:

- Limitations in decision-making capacity
- Situational circumstances (*e.g. coercion, dependency, or socio-economic pressures*)
- Increased risk of exploitation

Categories of Vulnerability:

Broad Types of Vulnerability:

- **Cognitive or Communicative:** diminished capacity to understand and/or communicate
- **Institutional:** being under formal authority structures (*e.g. prisoners, military personnel, residents in long-term care facilities*)
- **Deferential:** informal subordination to others due to social hierarchies (*e.g. power differentials based on gender, race, class, education*)
- **Medical:** presence of serious or chronic health conditions
- **Economic and/or Social:** disadvantage in access to social goods and services, or belonging to an undervalued group

Examples of Vulnerable Populations:

While vulnerability is context-dependent, certain groups may be more likely to require additional protections. These include, but are not limited to:

- Pregnant women (*see 45 CFR 46 Subpart B; [HRPP Policy 4.2](#)*)
- Fetuses and neonates (*Subpart B; [HRPP Policy 4.2](#)*)
- Prisoners (*Subpart C; [HRPP Policy 4.3](#)*)

- Children (*Subpart D*; [HRPP Policy 4.4](#))
- Decisionally impaired persons ([HRPP Policy 4.6](#))
- Critically ill persons
- Terminally ill persons
- Individuals who are blind, deaf, or have other disabilities
- Economically or socially disadvantaged persons
- Educationally disadvantaged persons
- Employees and students ([HRPP Policy 4.7](#))
- Non-English speaking persons
- **Note:** Vulnerability is not limited to inclusion in one of the categories above. Individuals may exhibit vulnerability due to unique personal or situational contexts. These groupings serve to assist in identifying potential risks and do not diminish the need for individualized assessment and protections.

Additional Protections for Vulnerable Populations:

Investigator Responsibilities for Assessing Vulnerability:

- **Necessity of Inclusion:** Investigators should assess
 - Is inclusion of vulnerable subjects scientifically and ethically justified?
 - Could research objectives be achieved with a less vulnerable population?
- **Adequacy of Protections:** Investigators must determine whether
 - Subjects can provide voluntary, informed consent
 - The consent process is understandable, comprehensible, and non-coercive
 - Subjects are protected from exploitation

Examples of Additional Protections:

Protections may include, but are not limited to:

- Use of an extended consent process
- Use of a consent monitor
- Appointment of a subject advocate
- Involvement of family members or trusted individuals in the decision-making process
- Requirement for re-consenting of subjects or LARs

- Imposing limits on allowable risk levels
- Increased data and safety monitoring
- More stringent subject withdrawal criteria
- Exclusion from participating in the research

Investigator Responsibilities:

- Must identify whether their research includes subjects covered under 45 CFR 46 Subparts B, C, or D or 21 CFR 56 Subpart D, including:
 - Pregnant women and fetuses
 - Prisoners
 - Children
- Must assess whether:
 1. Eligibility criteria will specifically target potentially vulnerable populations, or
 2. There is a high likelihood that a sizable number of subjects will come from a vulnerable population
- Must describe in the IRB application:
 - Any vulnerable populations expected to be enrolled
 - The specific additional protections that will be implemented
- If a subject becomes vulnerable after enrollment (*e.g. becomes incarcerated, pregnant, or homeless*), the PI must:
 - Assess and implement additional protections as needed, and notify the IRB
 - Evaluate whether changes are needed in the protocol or consent process for all subjects, and submit revisions to the IRB
 - Consult with the IRB regarding whether continued participation of the now-vulnerable subject is compliant with applicable regulations