Vulnerable Populations (HRPP 4.1)

Description:

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

Definitions:

Vulnerable Persons: individuals or groups "with diminished autonomy" or "have difficulty providing voluntary, informed consent arising from limitations in decision-making capacity… or situational circumstances… or because they are especially at risk for exploitation".

Individuals within a group of vulnerable subjects may have differing levels of vulnerability due to capacity, circumstance, or condition.

Broad Types:

- **Cognitive or Communicative-** diminished capacity to understand and/or communicate
- **Institutional-** subject to formal authority of others
- **Deferential-** informal subordination to others (gender, race or class inequalities, inequalities of power and knowledge)
- **Medical-** serious medical conditions
- **Economic and/or Social-** disadvantaged in distribution of social goods or services, or belonging to an undervalued group

Groups/Populations:

- Pregnant Women (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 (HRPP Policy 4.6)
- Critically ill
- Terminally ill
- Blind or deaf, or other disability
- Economically or socially disadvantaged
- Educationally disadvantaged

- Employees and students (HRPP Policy 4.7)
- Non-English speaking

Additional Protections to Consider:

It is the policy of UNMC that vulnerable populations will be afforded additional protections. Investigators should consider the following additional protections:

- Use of an extended consent process
- Use of a consent monitor
- Appointment of a subject advocate
- Involvement of the subject's friends and/or family
- Requirement for re-consenting of subjects/LARs
- Limits placed on risk
- Increased monitoring of research through the use of a Data Safety Monitoring Board (DSMB) or other mechanisms
- More stringent withdrawal criteria
- Longer study follow-up
- Exclusion from participating in research

General Requirements:

- The investigator must identify whether subject eligibility criteria will **specifically target** potentially vulnerable populations, or whether there is a high likelihood that a sizable number of subjects will come from a vulnerable population.
- The investigator must specifically describe additional protections for persons or populations identified in the IRB application in sections 7.1 and 7.2.
- If the IRB approves a protocol which does not involve vulnerable subjects but a subject, AFTER ENROLLMENT, becomes vulnerable, the PI must notify the IRB and revise the IRB application as applicable (ex. Subject is incarcerated, becomes pregnant, becomes homeless, etc.).