



Research Involving Prisoners (HRPP 4.3) (45 CFR 46 Subpart C)

Description:

This policy describes UNMC's requirements for IRB review and approval of research involving prisoners.

Definitions:

Prisoner: any individual INVOLUNTARILY confined or detained in a penal institution.

- **WOULD include:**
 - People detained in a residential facility for **court-ordered** substance abuse treatment
 - Individuals committed **involuntarily** to an institution for a psychiatric illness
- **WOULD NOT include:**
 - Individuals on probation or parole
 - Individuals who voluntarily admit themselves to an institution

Research Involving Prisoners:

Allowed only if it falls into **one of the four following categories:**

- 1) Study of the possible causes, effects, and processes of incarceration/criminal behavior
 - a. Must be minimal risk and minimal inconvenience
- 2) Studies on prisons as institutional structures or of prisoners as incarcerated persons
 - a. Must be minimal risk and minimal inconvenience
- 3) Research on conditions particularly affecting prisoners as a class
- 4) Research on innovative or accepted practices likely to improve the prisoner's health or well-being

IRB Review Considerations:

- Exempt review is not allowed
- **Monetary compensation of prisoners is not allowed**
- Addendum C (automatically populates in the application once you indicate prisoners will be included) required

Special Circumstances:

If a previously enrolled subject becomes a prisoner:

- You **must pause their participation**
- If the PI **believes it's in the best interest of the subject to continue** the research activities, a request may be made to the IRB
 - If the research is **NOT subject to 45 CFR 46 Subpart C**, then the IRB Executive Chair (or designee) may give temporary approval until the convened board has met and made their determination
 - If the research **IS subject to 45 CFR 46 Subpart C**, then they may resume participation only with convened board approval under Subpart C
 - In some cases, if policy and/or Subpart C requirements cannot be met, the board may decide to keep the participant enrolled or remove the participant from the study and keep them on the study intervention under an alternate mechanism
- If the **PI believes the subject should be withdrawn** from the research, the PI must make arrangement for continuation of any necessary treatment/care

Juvenile Detainees:

- Considered **both prisoners and children**- must apply both sets of protections