

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:

Research may involve prisoners **only if it falls into one of the following categories:**

- 1) Study of the possible causes, effects, and processes of incarceration and of criminal behavior.
 - a. Minimal risk and minimal inconvenience
- 2) Study of prisons as institutional structures or of prisoners as incarcerated persons.
 - a. Minimal risk and minimal inconvenience
- 3) Research on the conditions particularly affecting prisoners as a class.
- 4) Research on the practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject.

IRB Review Considerations:

- Expedited review not normally used.
- Exemption from IRB review not allowed.
- Monetary compensation of prisoners is not allowed.

If a Subject Becomes a Prisoner During Research (as determined by the Executive Chair or designee, in consultation as appropriate with the prisoner representative):

- The PI must report it to the IRB immediately. All research activities for that subject must stop until the protocol is re-reviewed.
- If the PI believes it is 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 a temporary approval until the full IRB has met and made their determination.
 - If the research IS subject to 45 CFR 46 subpart C, then the convened IRB will review to determine whether the requirements of 45 CFR 46 subpart C are met.
 - In either case, if some of the requirements of 45 CFR 46 subpart C or of this policy cannot be met, but it is in the best interests of the participant to continue the research activities, the board may decide to keep the participant enrolled or may remove the participant from the study and keep them on the study intervention under an alternate mechanism such as compassionate use or off label use.
- If the PI believes the subject should be withdrawn from the research, the PI must make provisions for the continuation of any necessary treatment.