Vulnerable Populations: Prisoners – Subpart C (HRPP 8.3)

MAY 2025 CONTINUING EDUCATION

Introduction:

- OHRP defines a Prisoner as: Any individual involuntarily confined or detained in a penal institution.
- Research involving prisoners can only be approved if the following regulatory requirements in 45 CFR 46.304 are satisfied:

1. The majority of the Board has no association with the prison(s) involved
   - Does not include prison members on the Board

2. At least one voting member of the Board must be a prisoner, or a prisoner representative with appropriate background and experience
   - The representative must be involved in the initial review, continuing review, review of amendments, and review of unanticipated problems

NOTE: If more than one Board needs to review the project, only one Board needs to satisfy this requirement

Incarceration of a Research Subject:

- If a subject becomes a prisoner during the research
  - PI must immediately notify the IRB
  - All research activities with that subject must be discontinued
    - Exception: The PI asserts in writing and the Chair agrees in writing that it is in the best interest of the subject to continue their participation
      - When making the determination, the Chair will consider:

      1. Does the research involve an intervention or procedure that holds out a prospect of direct benefit that is important to the health or well-being of the individual and is available only in the context of the research?

      2. Can the research be performed safely while the individual is a prisoner?

    - If the research can continue, it will need to be re-reviewed by the IRB in accordance with the additional protections for research involving prisoners

Categories of Research Involving Prisoners Allowable under 45 CFR46.306(a)(2):

1. Study of the causes, effects, and processes of incarceration/criminal behavior + presents no more than minimal risk and no more than an inconvenience

2. Study of prisons as institutional structures or of prisoners as incarcerated persons + presents no more than minimal risk and no more than an inconvenience

3. Research on conditions affecting prisoners as a class
   - The study may proceed only after the Secretary of HHS, (through OHRP), has consulted with appropriate experts and published notice, in the Federal Register, of the intent to approve such research

4. Research on practices that have the intent and probability of improving the health and well being of the subject
   - Studies that require the assignment of prisoners to control groups which may not benefit from the research - the study may proceed only after the Secretary of HHS, (through OHRP), has consulted with appropriate experts and published notice, in the Federal Register, of the intent to approve such research

5. Epidemiological Research addressing the prevalence, incidence, or risk factors for diseases that might affect prisoners + present no more than a minimal risk and no more than an inconvenience

IRB Deliberation and Documentation:

- When reviewing a protocol involving prisoners, the IRB must make and document the following findings:
  - The research represents one of the permissible categories
  - Any advantages gained by the prisoner by participating, when compared to the general living conditions, medical care, quality of food, amenities, and opportunity for earnings in prison, are not of such a magnitude that the individual's ability to weigh the risks of the research against the value of such advantages in the limited choice environment is impaired
  - The risks involved in the research = the risks for nonprisoner volunteers
  - Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners
    - Control subjects must be selected randomly from the group of prisoners who meet the required eligibility unless the PI gives reason for varying the selection process
  - The information is presented in lay language
  - Assurance exists that parole boards will not consider a prisoner's participation in making decisions regarding parole
  - If follow up care or examination of the participant is needed after the end of their participation, provisions have been made for the care/examination

- Documentation of these findings must be sent to OHRP
- Research cannot proceed until OHRP notifies the IRB in writing of their approval

Research Conducted within Bureau of Prisons:

- MUSC IRB, researchers, and research staff must follow the requirements of 28 CFR 512 including:
  1. The project must not involve medical experimentation, cosmetic research, or pharmaceutical testing
  2. The research design must be compatible with both the operation of prison facilities and protection of human subjects
     - The researcher must observe the rules of the institution or office in which the research is conducted
  3. Any researcher who is a non-employee of the Bureau must sign a statement in which the researcher agrees to adhere to the provisions of 28 CFR 512
  4. All research proposals will be reviewed by the Bureau of Prisons Research Review Board
- SC State Law also prevents payment to incarcerated participants
  - Needs to be included in the compensation section of the ICF and eIRB application

Procedures:

- In the Protocol, the PI will describe the rationale for including this vulnerable population and specify the applicable category
- The "Special Subject Populations – Prisoners" checklist will be used by the primary reviewers
  - One of the reviewers must be a prisoner representative
- The Board's discussion and decisions will be documented in the meeting minutes
  - If approved, the PI will be notified, and the following will be sent to OHRP:
    - Certification letter signed by the Chair
    - IRB application, approved research protocol, and all other materials submitted to the IRB
    - Any HHS grant application or proposal
  - All correspondence will be uploaded in eIRB
- Continuing review
  - Prisoner representative must review materials and participate in the meeting
  - If no subjects have been enrolled, the research may receive continuing review using the expedited procedure under expedited category #8
- Amendments
  - Prisoner representative must be included and participate in the review of modifications involving more than a minor change
  - Minor modifications to research may be reviewed using expedited procedures based on the type of modification

What questions do you have?