Prisoners as Human Research Subjects

Presentation for IRB Members
45 CFR Part 46 - DHHS Policy for Protection of Human Research Subjects - Subpart A

Also known as “The Common Rule” – Federal Policy for Protection of Human Subjects
Criteria For Approval of all Human Subjects Research

45 CFR Part 46.111 (Subpart A)

- Minimized risks
- Reasonable risk/benefit relationship
- Equitable subject selection
- Informed consent process
- Informed consent documentation
- Data monitored for safety
- Confidentiality/privacy maintained
- Vulnerable populations protected
Additional Protections Included in 45 CFR 46

**Subpart B** - Additional DHHS Protections Pertaining to Research, Development, and Related Activities Involving Pregnant Women, Fetuses, and Neonates (non-viable and those of uncertain viability)

**Subpart C** - Additional DHHS Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects

**Subpart D** - Additional DHHS Protections for Children Involved as Subjects in Research
Definition of Prisoner

• Any person confined or detained in a penal institution or,

• Individuals sentenced under criminal or civil statutes or,

• Individuals detained in other facilities by virtue of statute or commitment procedures which provide alternatives to criminal prosecution or incarceration or,

• Individuals detained pending arraignment, trial, or sentencing.
Definition of Minimal Risk for Prisoner Research

“Minimal Risk” is defined as the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

The definition of minimal risk for prisoners found in Subpart C differs from the definition of minimal risk in Subpart A of 45 CFR 46:

- focuses on physical and psychological harm
- comparison with healthy non-incarcerated population
Allowable Research

45 CFR Part 46.306 (a)(2)

- Study of possible causes, effects, processes of incarceration and criminal behavior; if the study involves no more than minimal risk and no more than inconvenience to the subjects

- Study of prisons as institutional structures or prisoners as incarcerated persons; if the study involves no more than minimal risk and no more than inconvenience to the subjects

- Research on conditions affecting prisoners as a class; requires OHRP and expert approval

- Research on practices (innovative and accepted) that have a reasonable probability of improving the health or well-being of prisoners; if study involves a placebo, requires OHRP and expert approval
Additional Criteria for Approval of HS Research per Sub Part C

- Fall within category of allowable research per 46.306 (a)(2)
- Ensure that the advantages of the research participation are not of such magnitude as to influence a prisoner’s ability to weigh risks and benefits
- Risks are commensurate with risk that might be assumed by non-prisoners
- Selection procedures are equitable among all prisoners and immune from arbitrary influence by prison authorities
Additional Criteria for Approval in Sub Part C (cont.)

- No influence on parole boards
- Information is in language understandable to prisoners
- Provisions are made for follow-up, if necessary
- For studies supported by the Department of Health and Human Services, the Institute must certify to the Secretary (through OHRP) that the IRB has made the seven findings required under 45 CFR 46.305(a), including the finding that the proposed research represents one of the permissible categories of research under 45 CFR 46.306(a)(2). For more information on this process, please refer to the following link:
  http://www.hhs.gov/ohrp/special/prisoners/
Other Criteria:

For research conducted within the Bureau of Prisons, the project must have an adequate research design and also contribute to the advancement of knowledge about corrections [Department of Justice (DoJ): 28 CFR 512.11(a)(2)].
IRB Composition for Prisoner Research

IRB meets all requirements of 46.107

In addition, per 45 CFR 46.304 the composition of the IRB when reviewing prisoner research must be addressed as follows:

- A majority of the Board (exclusive of prisoner members) shall have no association with the prisons involved, apart from their membership on the Board.
- At least one member of the Board shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one Board only one Board need satisfy this requirement.
It is important to note that the use of **prisoners in biomedical research is prohibited**. Biomedical research is defined by CA law as, “research relating to or involving biological, medical or physical science.”

Non-Human Subject Research: Research involving access to existing private de-identified information about prisoners does not constitute research involving human subjects. Moreover, research involving existing coded information about prisoners does not constitute research involving human subjects if both of the following conditions are met:
- 1) the private information was not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; and
- 2) the researchers cannot readily ascertain the identity of the individuals to whom the coded private information pertain because, for example the researchers and the holder of the key enter into an agreement prohibiting the release of the key under any circumstances, until the individuals are deceased.

Exempt Research: Revisions to the 2018 Common Rule now allow for the inclusion of prisoner subjects in exempt studies when the research examines a broader **subject population** and only incidentally includes prisoners.

Expedited Research: Per UCI policy, research involving access to private identifiable information about prisoners (coded identifiers only) but not involve intervention or interaction with prisoners, may be reviewed and approved under Expedited review.

Full Committee: Per UCI policy, research involving access to private identifiable information about prisoners (direct identifiers) or involve intervention or interaction with prisoners, requires initial Full Committee review.
Additional Important Points

- Subpart C applies whenever any human subject in an IRB-approved research protocol becomes a prisoner at any time during the study.

- When a previously enrolled research subject becomes a prisoner and the relevant research protocol was NOT reviewed and approved by IRB in accordance with the requirements Subpart C, the researcher should promptly notify the IRB of this event. All research interactions and interventions with, and obtaining identifiable private information about, the now-incarcerated prisoner-subject must cease until the requirements of subpart C have been satisfied with respect to the relevant protocol.

  **NOTE:** In special circumstances in which the researcher asserts that it is in the best interests of the subject to remain in the research study while incarcerated, the IRB Chair may determine that the subject may continue to participate in the research until the requirements of Subpart C are satisfied.

- An adolescent (e.g., age 14) detained in a juvenile detention facility is a prisoner therefore, the IRB would need to comply with Subpart C and Subpart D - Children.
Documentation – Subpart C in the IRB Application

• Investigators interested in enrolling prisoners as research subjects address additional questions when completing the IRB application or when requesting an amendment to an IRB-approved study.
Any Questions?

Contact HRP Staff!

This presentation was adapted from the Institutional Review Board: Management and Function, Amdur and Bankert, 2002
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