
Ethical Considerations for
Research Involving Prisoners:
A Report from the
Institute of Medicine

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Background/History

- National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research—1976
 - Resulted in DHHS regulation 45 C.F.R. Part 46 = Common Rule
 - Regulatory framework applied to 17 federal agencies conducting or funding human subjects research
 - Subpart C = additional protections for research involving prisoners

45 C.F.R. Part 46

- Institutional Review Boards (IRBs)
- Informed consent
- Institutional assurances

Subpart C

Prisoners as Research Subjects

- Categories of research permitted with prisoners:
 - Study of probable causes, effects & processes of incarceration
 - Prisons as institutional structures or prisoners as incarcerated persons
 - Conditions particularly affecting prisoners as a class
 - Practices that have the intent/reasonable probability of improving health/well-being of participants
- Additional requirements for IRBs
- Office of Research Protections certification

Shortcomings of Common Rule

- Applicable only to DHHS-funded projects (single federal regulation for federally-funded projects only)

Changes in Prison Population

- Escalating population
- Overrepresentation of racial/ethnic minorities
- Increased over-crowding -> less availability of programs/services
- Inadequate health care services
- Increasing population of females
- Increasing numbers of alternative programs
- Overrepresentation of communicable diseases
- Increasing admissions of mentally ill prisoners

Change in Health Issues

- High rates of HIV/AIDS, hepatitis, TB
- Prisons as new mental illness asylums
- Aging population -> chronic diseases of DM, HPTN
- Substance abuse

Question

Given these changes in prison populations, health problems and inadequate health services was 45 CFR Part 46 (Common Rule) adequate to protect prisoners from research exploitation?

Were additional protections required to ensure prisoners' rights?

DHHS office of Human Research Protections
commissioned Institute of Medicine to review
ethical considerations on research regarding
prisoners

5 New Recommendations

- Expand definition of the term “prisoner”
- Ensure universally/consistently applied standards of protection
- Shift from a category-based to a risk-benefit approach to research review
- Update ethical framework to include collaborative responsibility
- Enhance systematic oversight of research involving prisoners

Recommendation 1:

Expand definition of term “prisoner”

Regulations apply to any:

- State or federal prison
- Jail or detention facility
- Community-based criminal justice supervision program
- Community-based alternative disposition program

Also, individuals committed on mandatory or involuntary basis to:

- Psychiatric treatment facilities
- Drug/ETOH treatment facilities
- Other treatment settings

Recommendation 2:

Ensure universally/consistently applied standards of protection

- Should apply to all research involving prisoners regardless of source of funding, supporting agency or type of facility
- All research under OHRP oversight

Recommendation 3:

Shift from a category-based to a risk-benefit approach to research review

- Balance between strong protectionism
VS.
 - Understanding of research as a potential benefit
 - Prisoners' rights to participate in research
VS.
 - Difficulty in obtaining true informed consent
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Recommendation 4: Update ethical framework to include collaborative responsibility

- Obtain input from prisoners and other stakeholders (responsibility of researchers)
- Ensure adequate standards of care
- Support critical areas of correctional research

Recommendation 5:

Enhance systematic oversight of research involving prisoners

- Establish public database of research involving prisoners; DHHS in cooperation with DoJ
- Ensure transparency & accountability in research endeavors

Current Status of Recommendations