



Human Research Protection Program

Institutional
Review
Board (IRB)
Researcher
Education
Series

VULNERABLE
POPULATIONS
SUBPART C: PRISONERS

Defining Vulnerable Populations

"Vulnerability, in the context of research, should be understood to be a condition, either intrinsic or situational, of some individuals that puts them at greater risk of being used in ethically inappropriate ways in research" (National Bioethics Advisory Counsel, 2001)

Two general themes:

1. Have difficulty providing voluntary, informed consent arising from limitations in decision-making capacity or situations circumstances
2. Especially at risk for exploitation or coercion

Vulnerable Populations as defined by DHHS

As defined in the Common Rule:

subpart B: Pregnant Women, Fetuses, & Neonates

subpart C: Prisoners

subpart D: Children

Adults with Impaired Decision-Making Capacity

While the subparts outline additional requirements for each vulnerable population, those requirements are in addition to the ones outlined in 45 CFR 46 which apply to all research conducted using Human Subjects.

History of Prisoners as Test Subjects in Research

Up to the late 1960s:

- Research involving prisoners as test subjects was generally acceptable and did not require any additional oversight

Early 1970s:

- Major research scandals came to light causing major scrutiny on the ethics of using prisoners in research

1976:

- Federal Bureau of Prisons and 8 states formally moved to abandon research in prisons

1978:

- 45 CFR 46, subpart C is adopted, outlining strict requirements for prisoner participation in research

Why Prisoners are Considered Vulnerable

Due to their incarceration:

- Their ability to make an informed and voluntary decision is compromised.
- Constraints may affect their ability to make an un-coerced decision.
- The risk of exploitation is high.

Defining Prisoners

- Any person "involuntarily confined or detained in a penal institution" as a result of violating a criminal or civil statute,
- Any person "detained in other facilities by virtue of states or commitment procedures which provide an alternative to criminal prosecution or incarceration in a penal institution, and,
- Individuals detained pending arraignment, trial, or sentencing"

[45 CFR 46.303(c)]

Defining Prisoners

subpart C also applies to:

- Unanticipated inclusion of of a prisoner in the research of an institution
- Subjects who become prisoners following enrollment in a study

**Both circumstances must be reported to the IRB for review*

subpart C does not apply to:

- Subjects attending mandated treatment while residing in the general public
- Subjects on probation or parole
- Subjects who voluntarily undergo substance abuse treatment
- Subjects who are civilly committed

Categories of Permitted Research

1. Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no greater than minimal risk and no more than inconvenience to the subject

[45 CFR 46.306(a)(2)(i)]

Examples:

- Secondary research analysis
- Social-behavioral research
- Longitudinal studies where recidivism is an outcome measure

[Institutional Review Board Management & Function, 3rd Edition]

Categories of Permitted Research

2. Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subject

[45 CFR 46.306(a)(2)(ii)]

Examples:

- Examination of nicotine addiction cessation programs in prison
- Peer-mediated end-of-life caregiving among prisoners
- Cancer disparities in incarcerated men

[Institutional Review Board Management & Function, 3rd Edition]

Categories of Permitted Research

3. Research on conditions particularly affecting prisoners as a class... provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of intent to approve such research
[45 CFR 46.306(a)(2)(iii)]

*This category does not limit risk and does not require prospective benefit

Examples:

- Examination of novel antiretroviral therapy for HIV treatment

[Institutional Review Board Management & Function, 3rd Edition]

Categories of Permitted Research

4. Research on practices, both innovative & accepted, which have the intent and reasonable probability of improving the health and well-being of the subject. In cases in which those studies require assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups, the study may proceed only after the Secretary has consulted with appropriate experts and published notice in the Federal Register of intend to approve such research.

[45 CFR 46.306(a)(2)(iv)]

Examples:

- Comparative effectiveness studies

[Institutional Review Board Management & Function, 3rd Edition]

2003 Epidemiologic Waiver

Studies that meet the following criteria:

1. In which the sole purposes are

(i) to describe the prevalence or incidence of a disease by identifying all cases, or

(ii) to study potential risk factor associations for a disease;

and

2. Where the institution responsible for the conduct of the research certifies to OHRP, acting on behalf of the Secretary, that the IRB approved research and fulfilled its duties under 45 CFR 46.305(a)(2)-(7) and documented that

(i) the research presents no more than minimal risk and no more than inconvenience to the subject

(ii) Prisoners are not a particular focus of the research.

[45 CFR 46.301(i)]

Requirements for Prisoner Participation

1. Research must fall into one of the categories of research permissible
2. Any possible advantages accruing to the prisoner through their participation in the research, when compared to general living conditions, medical care, quality of food, amenities, or opportunities for earnings in the prison, are not of such a magnitude that their ability to weigh the risks of the research against the value of such advantages in the limited choice environment of a prison is impaired
3. The risks involved in the research are commensurate with risks that would be accepted by a non-prisoner volunteer

Requirements for Prisoner Participation

4. Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or other prisoners
5. Information is presented in a language which is understandable to the subject
6. Adequate assurance exists that parole boards will not take into account a prisoner's participation in research when making a decision regarding parole
7. If there is a need for follow-up examinations or care after participation, adequate provisions have been made taking into account the varying lengths of sentences

Additional Resources

45 CFR 46, subpart C

<https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-c/index.html>

subpart C Certification Request

<https://www.hhs.gov/ohrp/regulations-and-policy/subpart-c-certification-request-to-ohrp/index.html>

LSUHSC - NO HRPP Policies and Procedures 7.01

https://www.lsuhs.edu/administration/academic/ors/policies_procedures.aspx