Research Involving Prisoners

1 Introduction and Background

In 1976, the U.S. National Commission for the Protection of Human Subjects issued a report on the issues involved with performing experiments on prisoners. In 1978, the U.S. Department of Health and Human Services issued regulations addressing prisoners as a vulnerable research population (45 CFR 46 Subpart C; this link will launch a new browser window).

These regulations were developed as a result of the exploitation of prisoners to test drugs and medical devices during the middle decades of the twentieth century. For example, it is estimated that after 1962, 90% of pharmaceuticals were first tested in prison populations. This section addresses some of the important matters researchers should consider when they wish to study prisoners.

1.1 Why do prisoners need special protections?

The National Commission presented several reasons that supported special protections for prisoners as research subjects:

- The ability of prisoners to exercise free choice may be limited because their autonomy is restricted. They may be concerned about repercussions if they refuse to participate in the research.

- Confidentiality of participation and of data are difficult to maintain in a prison setting because privacy of inmates is severely limited and prison spaces may be subject to monitoring such as audio and visual recordings.

- Inducements offered by researchers to prisoners may create undue influence. Prisoners are paid low wages and have limited access to money. An inducement to participate may appear much more valuable to a prisoner than it would to a non-prisoner.

- Prisoners may represent a population of convenience for researchers rather than a truly representative or inclusive study population. Studies of medical products on prisoners are quicker and cheaper than doing these studies in a non-incarcerated clinical population because the confounding variables can be reduced.

- Prisoners may not realize benefits from participating in research that non-incarcerated subjects may be offered. Their options for health care, education, and social services are limited by virtue of their incarceration and social and economic status.

1.2 Who is a prisoner?

What the regulations say…

The word "prisoner" is defined in 45 CFR 46.303(c) as follows:

> "A Prisoner means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing."

Rough translation:

> Prisoners are people who are being held in a jail, prison, or treatment facility or who have been convicted or are awaiting arraignment, trial, or sentencing. This includes those who are in hospitals, alcohol, and drug treatment facilities under court order. The definition applies to minors as well as to adults.

2 What kinds of research with prisoners are allowed?

The regulations allow prisoners to be involved in four categories of research:

2.1 Category 1

Studies of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than *minimal risk* and no more than inconvenience to the subjects (examples of this kind of research might involve demographic studies of rates of incarceration or records-based studies of recidivism).

2.2 Category 2

Studies 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 subjects (examples of this kind of research might involve confidential surveys of prisoners regarding food service or educational opportunities).

2.3 Category 3

Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) and

2.4 Category 4

Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well being of the subject. (Examples of this kind of research might include studies on alternative sentencing or clinical trials of cancer therapies that do not involve assignment to placebo.)

Most studies in categories 3 and 4 may proceed only after the Secretary of DHHS has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice in the **Federal Register** of the intent to approve such research.

OHRP has to be notified about the research in all categories if the study is funded by DHHS. The only exception for DHHS secretary approval appears to be in category 4 if the study holds out potential benefits for prisoner-subjects and does not include the possibility of assigning them to a placebo or no treatment condition.

3 What does the IRB have to do in order to review research involving prisoners?

- A majority of the IRB members (excluding prisoner members) must have no association with the prison(s) involved, apart from their membership on the Board.

- At least one member of the IRB must be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity. If a research project is being reviewed by more than one IRB only one IRB must satisfy this requirement. Suitable individuals could include prison chaplains, prison psychologists, prison social workers, or other prison service providers; persons who have conducted advocacy for the rights of prisoners; or any individuals who are qualified to represent the rights and welfare of prisoners by virtue of appropriate background and experience.

4 What must the IRB determine in order to approve research involving prisoners?

The IRB must determine that:

- The research under review falls into one of the categories of research allowed under Section 46.306(a)(2).

- Any benefits to the prisoner which may result from being in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, do not impair his or her ability to weigh the risks of the research against the benefits in the prison environment.

- The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers.

- Procedures for the selection of subjects within the prison are fair to all prisoners and control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project.

- The study information is presented in language which is understandable to the subject population.

- Parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is

clearly informed in advance that participation in the research will have no effect on his or her parole.

- Adequate provisions have been made for follow-up examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

5 What if an already enrolled subject becomes a prisoner?

The regulatory protections are applicable to all prisoner-subjects, regardless of their status at the time of enrollment in a study. OHRP does not require immediate suspension of research activities when a subject becomes a prisoner. Rather, OHRP recommends that:

1. Investigators inform the IRB immediately upon learning that a subject has entered prison.
   AND
2. The IRB review the protocol "at the earliest opportunity" to determine whether continued participation in the research is appropriate under the regulations.

See OHRP Guidance on Approving Research Involving Prisoners. This link will launch a new browser window. Close the new window to return here.

Subjects involved in research on practices "which have the intent and reasonable probability of improving the health or well-being of the subject" are eligible to continue their participation with absolutely no interruption, as are subjects involved in the other categories described in the regulations.