Research Involving Prisoners

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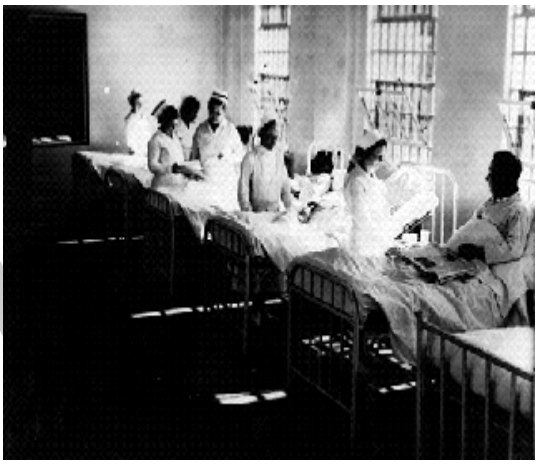
Introduction



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, until the early 1970s, nearly 90% of all new pharmaceuticals were first tested in prison populations (see article by T.J Wiegand MD). This section addresses some of the important matters researchers should consider when they wish to study prisoners.

Learning Objectives

After completing this module you should be able to:

- Describe the regulatory definition of a prisoner.
- List the categories of research permitted with prisoners.
- Identify the IRB membership requirements required for approval of research with prisoners.
- Describe the items the IRB must determine in order to approve research involving prisoners.

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 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.

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, juvenile offender facility, 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.

According to OHRP, some common examples of the application of the definition of prisoner:

- Individuals who are detained in a residential facility for court-ordered substance abuse treatment as a form of sentencing or alternative to incarceration are prisoners; however, individuals who are receiving non-residential court-ordered substance abuse treatment and are residing in the community are not prisoners.

- Individuals with psychiatric illnesses who have been committed involuntarily to an institution as an alternative to a criminal prosecution or incarceration are prisoners; however, individuals who have been voluntarily admitted to an institution for treatment of a psychiatric illness, or who have been civilly committed to nonpenal institutions for treatment because their illness makes them a danger to themselves or others, are not prisoners.
- Parolees who are detained in a treatment center as a condition of parole are prisoners; however, persons living in the community and sentenced to community-supervised monitoring, including parolees, are not prisoners.
- Probationers and individuals wearing monitoring devices are generally not considered to be prisoners; however, situations of this kind frequently require an analysis of the particular circumstances of the planned subject population. Institutions may consult with OHRP when questions arise about research involving these populations.

Minimal risk is also defined differently:

Non-Prisoner Minimal Risk is defined in 45 CFR 46.102(i) as follows: Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests

Prisoner Minimal Risk is defined in 45 CFR 46.303(d) as follows: Minimal risk is 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.

According to OHRP:

- The subpart C definition [Prisoner Minimal Risk definition] refers to physical or psychological harm rather than harm or discomfort as in subpart A [Non-Prisoner Minimal risk definition].
- The subpart C definition compares the probability and magnitude of harm in the research to the probability and magnitude of those harms normally encountered in daily life, or in routine medical, dental, or psychological examinations, rather than in daily life or routine physical or psychological examinations or tests as in subpart A.
- The subpart C definition identifies healthy persons as the comparison group against which the risks of the research should be measured, rather than leaving the comparison group unspecified, as in subpart A. OHRP interprets the term healthy persons in this definition as referring to healthy persons who are not prisoners.

What kinds of research with prisoners are allowed?

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

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* of harm 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).

Category 2: Studies of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than *minimal risk* of harm 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).

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

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 HHS 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 must be notified about the research in all categories if the study is funded by HHS. The only exception for HHS 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.

In addition to the aforementioned categories, there is also the HHS Secretarial waiver for certain epidemiological research conducted or supported by HHS. The criteria for this category is that the research must have as its sole purpose (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. The institution still must review the research under subpart C and certify to OHRP that an appropriately constituted IRB has reviewed the proposal, made all other required findings under HHS regulations at 45 CFR 46.305(a), and receive OHRP authorization prior to initiating any research involving prisoners. All of the other requirements of subpart C apply to research in this category.

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.

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 that 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.

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. If a previously enrolled research subject becomes a prisoner and the study was not reviewed and approved by the IRB in keeping with Subpart C, then OHRP guidance requires immediate suspension of research activities (including collection of identifiable private information) until the study can be reviewed in keeping with the requirements of Subpart C. The researcher should notify the applicable IRB promptly. OHRP guidance includes one important exception to the requirement to suspend activities. 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.

Once the IRB receives notice that the subject has become a prisoner, the IRB should review the protocol promptly in keeping with the requirements of Subpart C if the researcher wishes to have the subject continue in the research.

See *OHRP Guidance on the Involvement of Prisoners in Research*. This link will launch a new browser window. Close the new window to return here.

Research Involving Prisoners

An investigator wants to conduct a U.S. Centers for Disease Control and Prevention (CDC) funded study of the safety of a vaccine to prevent hepatitis C involving prisoners as subjects. Prisoners will receive either vaccine or placebo, and then be asked to complete surveys and undergo physical exams to assess for adverse effects. In order to assure that subjects will report side effects and cooperate with exams, prisoners who are judged by the guards to be most compliant and well-behaved are non-randomly assigned to the experimental arm; others are assigned to the control (placebo) arm. To encourage participation, prisoners are offered better meals and the opportunity for better paying jobs in the prison. During the convened IRB's review, the following statements are made:

QUESTIONS:

- The IRB Chair says, "There is no prospect for direct benefit to all subjects; therefore the research is not approvable." Is this correct?

No, the IRB Chair is mistaken. Research approvable under 45 CFR 46, Subpart C must be reviewed by an IRB appropriately constituted (§46.304), satisfy additional requirements (§46.305), fall into one of four allowable categories (§46.306), and possibly require review and approval by the secretary of DHHS (§46.306(a)(2)(iii) and (iv)). **There is no requirement in Subpart C that research provide direct benefit to all subjects.** It is important to remember, however, the research must also satisfy requirements of §46.111, including that "Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result."

- The prisoner representative says, "It does not seem that procedures for the selection of subjects within the prison are fair. The research is not approvable." Is this correct?

Yes, the prisoner representative is right. Subpart C specifies that "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" (§46.305(a)(4)). It does seem that the procedures for the selection of subjects are not fair since subjects will be subjectively assigned to a group, and therefore the proposed study as presented is not approvable.

- The unaffiliated member says, "Benefits appear to be excessive and perhaps would represent undue influence. The research is not approvable" Is this correct?

Yes, the unaffiliated member is right. Subpart C specifies that "Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired" (§46.305(a)(2)). It does seem that benefits appear to be excessive and perhaps would represent undue influence; therefore the research is not approvable.

- The nurse manager on the IRB says, "Even if we found this acceptable, the research must be reviewed and approved by the Secretary of U.S. Department of Health and Human Services." Is this correct?

Yes, the nurse manager is right. This research would probably fall into category 3 as "Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis …)". For this category, Subpart C notes 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 his intent to approve such research" (§46.306(a)(2)(iii)).

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