

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH	Human Research Protection Program Policies & Procedures	
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Title: Research Involving Prisoners	Date Effective 6/29/04	Supercedes P&P dated

Background

Prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research. Thus, Federal regulations require that IRBs apply additional safeguards for the protection of prisoners involved in research. These concerns and requirements apply whether the research involves individuals who are prisoners at the time of enrollment or become prisoners after they are enrolled in the research.

JHSPH POLICY AND PROCEDURES

Except as noted below, all biomedical and behavioral research involving prisoners, either as the subject population or as subjects who become prisoners after enrollment, and regardless of funding source, must be reviewed and approved by the CHR prior to initiating the research. The categories of permissible research and the additional review requirements for research involving prisoners are described below.

Categories of Research Permissible Under the Federal Regulations

1. The research is minimal risk and no more than an inconvenience to subjects and the research is a study of the possible causes, effects, and processes of incarceration and of criminal behavior. (45 CFR 46.306(a)(2)(A))
2. The research is minimal risk and no more than an inconvenience to subjects and the research is a study of prisons as institutional structures or of prisoners as incarcerated persons. (45 CFR 46.306(a)(2)(B))
3. The research is a study on conditions particularly affecting prisoners as a class (i.e., vaccine trials relating to hepatitis and research on social and

psychological problems such as alcoholism, drug addiction, and sexual assaults). 45 CFR 46.306(a)(2)(C)

4. The research is a study on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health and well being of the subject. However, if the study involves a control group that may not benefit, it requires the additional approval of the Secretary, DHHS. (45 CFR 46.306(a)(2)(D))
5. The research is federally funded and minimal risk and no more than an inconvenience to subjects and prisoners are not a particular focus of the research and the sole purpose of the research is to describe the prevalence or incidence of a disease by identifying all cases or to study potential risk factor associations for a disease.

Additional Requirements for Research That Involves Prisoners

In addition to the usual requirements for approval, CHR must also determine that:

1. the research under review represents one of the above categories of permissible research;
2. 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;
3. the risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;
4. procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the IRB justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;
5. the information is presented in language which is understandable to the subject population;
6. adequate assurance exists that 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; and
7. where the IRB finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

Research Involving Prisoners as the Subject Population

If it is proposed in a new research application that prisoners be included, the project will be reviewed by CHR with special consideration given to the 7 additional findings listed above. The investigator must complete the [Prisoner Checklist, CHR Form I](#), and attach it to the application. Contact with prisoners may not begin until CHR has approved the study.

Research Involving Subjects Who Become Prisoners After Enrollment

If the investigator becomes aware of a subject who becomes a prisoner *after enrollment*, the investigator should notify ORS immediately by submitting a memorandum requesting an amendment to the project for inclusion of prisoners, along with a completed [Prisoner Checklist, CHR Form I](#). All research interactions and interventions with, and obtaining identifiable private information about, the now-incarcerated prisoner-subject must cease until the additional requirements described above have been satisfied with respect to the relevant protocol. In special circumstances in which the principal investigator asserts that it is in the best interests of the subject to remain in the research study while incarcerated, the CHR Co-Chair may determine that the subject may continue to participate in the research until the additional requirements are satisfied.

In certain populations, such as drug-users, the likelihood that some subjects may become incarcerated during a study is increased. If this is anticipated, it should be stated in the application and the [Prisoner Checklist, CHR Form I](#) should be completed. CHR may also note this possibility at the time of initial review and recommend that the investigator indicates that prisoners may be involved in the research and that the checklist be completed. In either case, CHR would then review the application based on the additional Federal requirements for approval of research involving prisoners.

Required Review by OHRP

All research involving prisoners that is funded by HHS must be reviewed and approved by OHRP, in addition to approval by CHR. The process is as follows:

1. When CHR approves the research, it will send a certified letter with a copy of the proposal to OHRP for review.
2. CHR will notify the investigator of its recommendation and, when received, that of OHRP.

NOTE: Research with prisoner(s) may not proceed until the Committee *and* OHRP approve the research, unless the CHR Co-Chair determines it is in the best interest of the subjects to proceed.

Definitions

Prisoner. Any individual involuntarily confined or detained in a penal or correctional 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. (45 CFR part 46.303(c))

Minimal Risk Research as it applies to research involving prisoners. 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. (45 CFR 46.303(d)). The risks to which prisoners may be exposed are those compared with routine daily life and not those to which prisoners would normally encounter as prisoners.