

Issuing Department: Human Subjects Protection Program (HSPP)
Policy Number: 2011-006.2
Policy Title: Additional Protections for Certain Populations: Prisoners

Purpose

The purpose of this policy is to set forth the requirements of the HSPP for review and approval by the Institutional Review Board of studies intending to involve prisoners as subjects.

Definitions

See Policy 2011-007.0 for definitions of the following terms:

Risk, Minimal | Risk, Minimal for Prisoners | Secretary | Prisoner

Policy

Studies intending to involve prisoners as subjects do not qualify for exemption. However, studies aimed at involving a broader subject population that only incidentally include prisoners may qualify for exemption.

For non-exempt studies intending to involve prisoners as subjects the additional protections for the inclusion of prisoners in research apply in the following circumstances:

- The research is federally funded or supported; or
- The research is intended to involve interaction or intervention with prisoners.

When the additional protections apply, except as noted below, the convened board must review all studies intending to involve prisoners as subjects.

- Federally funded studies for which the entire activity is limited to chart reviews may be reviewed and approved by the Chair and Prisoner Representative through expedited review providing there is an appropriate expedited category under which to approve the research.
- Requests for expedited approval of a modification may be reviewed by any experienced member of the IRB, providing the modification does not relate to a change in study design or procedures. For example, any IRB member may approve a change in staff or clarification of wording. For changes to study design or procedures (e.g., addition of a blood draw); review will be done by the Chair and prisoner representative; and either of them may determine review by the convened board is required.
- Once the remaining activity is limited to data analysis or long-term follow-up if continuing review is required, any experienced member of the IRB may conduct the review.
- Any experienced member of the IRB or experienced member of the IRB/HSPP support staff may review responses to contingencies for purposes of issuing the final approval to a submission.

When reviewing studies that will involve prisoners as subjects, the membership of the board will be such that the majority of members (exclusive of prisoner members) have no association with the prisons involved and at least one member will be a prisoner, or a prisoner representative.

In assessing the level of risk involved in a study the IRB will not use risks that face prisoners in the prison setting as the standard for acceptable risk and will only allow risks that are commensurate with those that would be accepted by non-prisoner volunteers.

When reviewing research intending to involve prisoners the IRB will ensure that the research is permissible under one of the following categories:

- study 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;
- 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 subjects;
- research on conditions particularly affecting prisoners as a class (e.g., 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). For research funded by the Department of Health and Human Services (DHHS), 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; or
- research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. For DHHS-funded research, in cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, 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.

The IRB may approve research involving prisoners if the IRB finds that the research satisfies the conditions of all applicable sections noted below:

- 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;
- 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 immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the Board 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;
- the information is presented in a language which is understandable to the subject population; (note: use a 5th grade reading level as a benchmark)
- 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
- where the Board 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 prisoner's sentences, and for informing participants of this fact.

When funding is from DHHS, the institution shall certify to the Secretary, in such form and manner as the Secretary may require, that the duties of the Board under Subpart C have been fulfilled. The certification letter will be prepared by IRB staff and sent from the IRB Chair.

Unexpected Incarceration of Enrolled Subject:

If a participant becomes a prisoner while enrolled in a federally funded or supported non-exempt research study that did not intend to enroll prisoners and was not previously reviewed according to the special protections afforded to prisoners (i.e., Subpart C of 45 CFR 46), and the PI has confirmed that the participant meets the definition of a prisoner the following apply:

- Report the incarceration to the IRB on a Problem Report Form
- Include on the form plans to either terminate enrollment of the subject in the study; or to request that the IRB review the research study under Subpart C if it feasible for the participant to remain in the study.
 - Before terminating the enrollment of the incarcerated participant, the PI and IRB should consider the risks associated with terminating participation in the study.
 - If the participant cannot be terminated for health or safety reasons, review of the research under Subpart C must be obtained.
 - If some of the requirements of Subpart C cannot be met, but it is in the best interests of the participant to remain in the study, keep the participant enrolled and for DHHS supported research, inform the Office of Human Research Protections (OHRP) of the decision along with the justification.
- Alternatively, remove the participant from the study and keep the participant on the study intervention under an alternate mechanism such as compassionate use, off label use, etc.

Epidemiologic Research Involving Prisoners:

Effective June 20, 2003, the Secretary of the DHHS may also approve epidemiologic research involving prisoners as subjects under a provision allowing for a waiver of the applicability of provisions of 45 CFR 46.305(a)(1) and 46.306(a)(2). While prisoners may be included in such studies, they cannot be the only population included within the study. The epidemiologic research can present no more than minimal risk and no more than inconvenience to the prisoner-subjects. To qualify for such a waiver the epidemiologic study must meet the following criteria:

- the sole purposes are to describe the prevalence or incidence of a disease by identifying all cases, or to study potential risk factor associations for a disease, and
- for DHHS supported research, the IRB, via a letter prepared by the IRB staff and signed by the Chair, must include in the certification letter to the Office for Human Research Protections that:
 - the additional criteria, as described above, have been satisfied.
 - that the research presents no more than minimal risk and no more than inconvenience to the prisoner-subjects, and
 - prisoners are not a particular focus of the research.

Studies for which the waiver may apply include epidemiological research related to chronic disease, injuries, and environmental health.

Procedure

See policy 2011-006.0 – Additional Protections for Certain Populations: General

- review by expedited procedures is only allowed in circumstances described above.

In addition, for studies presented to the convened board the IRB chair will assign a prisoner representative as one of the primary reviewers. However, exceptions delineated in policy 2011-006.0 may apply.

For DHHS funded research, the assigned Regulatory Specialist will use the standard Prisoner Certification Template Letter to prepare the required certification letter for signature of the IRB Chair and send the letter to

the Secretary through the Office of Human Research Protections. The RS will include a statement in the standard IRB approval letter that prisoners may not be involved until such time as DHHS has provided documentation of its review and concurrence that the research is approvable.

Related Policies

- 2011-006.0 – Additional Protections for Certain Populations – General
- 2011-007.0 – Definitions
- 2011-009.3 – Institutional Review Board – Expedited Reviews
- 2011-009.5 – Institutional Review Board – Review by Convened Board

Basis

- 45 CFR 46
- 67 FR 62432, October 7, 2002 for Epidemiologic Waiver

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