

Status **Active** PolicyStat ID **13321498**



**Boston
Children's
Hospital**

Where the world comes for answers

Effective 1/1/2023
Next Review 1/1/2026

Owner Susan Kornetsky:
Manager
Department Research
Applicability Boston Children's
Hospital- Policies
& Procedures

Incarcerated Youth and Prisoners Policy/Procedure

Internal Approval

SVP, Research

EVP & Chief Scientific Officer, Research

Scope

This policy describes the additional responsibilities and procedures the Institutional Review Board (IRB) must undertake in its review of protocols that involve prisoners as subjects.

Definitions

Minimal risk: 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)).

Definition of Minimal Risk as it Applies to Prisoners/Incarcerated Youth

The wording of the subpart C definition differs in several ways from the definition of "**minimal risk**" in subpart A of 45 CFR part 46, which applies generally to research involving human subjects. The subpart C differences are:

1. The definition refers to "physical or psychological harm" rather than "harm or discomfort" as in subpart A.
2. The 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.

3. The 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.

Prisoner: 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 that provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

Policy Statements

Boston Children's Hospital IRB reviews all federally funded research that involves prisoners as subjects, in accordance with the Department of Health and Human Services (HHS) regulations for the protection of human subjects (45 CFR 46, Subpart C) that provide additional protections for biomedical and behavioral research.

Equal protections are used when the research is not federally funded.

Exemptions do not apply to research involving prisoners except for research aimed at involving a broader subject population that only incidentally includes prisoners.

For research involving prisoners that is subject to Department of Defense regulation, additional protections apply.

Documentation of IRB Findings

The HHS regulations at subpart C require that the IRB make and document specific findings when approving research that involves prisoners. As part of its review process, the IRB requires investigators to document how the findings will be met. Documentation of the findings are to be included in the IRB minutes.

Procedures

Procedures provides detailed procedural requirements, step, methods and guidance on how covered persons are expected to perform recognizing every case and patient are different [in accordance with the policy].

1. Example
 - a. Example

The IRB is to ensure that the following conditions are met:

Subpart C Applies Where any Subject is or Becomes a Prisoner

The provisions of Subpart C apply to any research funded by Department of Health and Human Services (HHS) that involves prisoners as subjects. This includes situations in which a human subject:

1. Is a prisoner when they are enrolled in the research; or

2. Becomes a prisoner after the research commences.

Special Composition of IRB and Reviewers Required for Convened IRB and Expedited Reviews

The IRB must meet the special composition requirement for the convened IRB review of new protocols, continuing reviews, and protocol amendments:

1. A designated prisoner representative must be present as a voting IRB member at all convened IRB meetings at which protocols that involve prisoners are reviewed that involve HHS funding.
 - a. This individual is to have the appropriate background and experience to serve in this capacity, including a close working knowledge of prison conditions and prison life.
2. In addition, most of the IRB (exclusive of prisoner members) will have no association with the prison involved, apart from their membership on the IRB.
3. The IRB prisoner representative will be assigned as a primary or secondary reviewer for all protocols, continuing reviews, and amendments that involve incarcerated youth/prisoners.

When expedited review procedures are utilized, the prisoner representative must be assigned: all protocols, continuing reviews, and amendments for those protocols that involve prisoners and incarcerated. Other members may be assigned in addition to the prisoner representative.

Single IRB Review

If a protocol is to be reviewed by more than one IRB, only one of the reviewing IRBs must meet this requirement.

Initial Expedited Review Process

To undergo initial expedited review, review modifications, and continuing reviews the submission must:

1. Meet the definition of minimal risk as defined above.
2. Be eligible for expedited review in accordance with the approved list of expedited review categories.
3. The prisoner representative must concur with the determination that the research involves no greater than minimal risk.

Research that does not involve direct interaction with prisoners (e.g. existing data, record review, etc.) may be reviewed by the expedited procedure, if a determination is made that the research involves no greater than minimal risk for the prison population being studied. Review by a prisoner representative is not required.

Additional Duties of the IRB Where Prisoners are Involved

The IRB must make the following **seven findings** when reviewing a protocol that involves prisoners as subjects:

1. The protocol under review falls within one of the categories of permissible research. These

categories are as follows:

The research in categories (A) and (B) must be minimal risk research, as specified in subpart C.

- i. Study of the possible causes, effects, 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.
- ii. 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.

The research in categories (C) and (D) may require Office for Human Research Protection (OHRP) review by appropriate experts and may require that a notice of intent to approve the research be published in the Federal Register if federally funded.

- i. Research on conditions particularly affecting prisoners as a class (i.e., 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) 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 the intent to approve such research
- ii. Research on practices, both innovative and accepted, that have the intent and reasonable probability of improving the health or well-being of the subject. 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 the intent to approve such research.

Please note that paragraph (D) requires OHRP to consult with appropriate experts if the research involves a control group.

2. Any advantages that may accrue to the prisoner through their 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 a magnitude that may impair their ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison.
3. The risks involved in the research are commensurate with risks that would be accepted by non-prisoner 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 the IRB with written justification for following some other procedure, 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 that is understandable to the subject population.
6. Adequate assurance exists that parole boards will not consider a prisoner's participation in the research when making decisions regarding parole and each prisoner is clearly informed in advance that participation in the research will have no effect on their parole.
7. Where the IRB determines the need for follow-up examination or care of subjects subsequent to their participation, adequate provision is made for such examination or care that takes into consideration the varying lengths of prisoner sentences, and adequate provision is made for informing participants of the need for follow-up examination or care.

Federally Funded Research Involving Prisoners

HHS-supported research that involves prisoners requires the following **two** actions:

1. The IRB must certify to the Secretary Office of Human Research Protections (OHRP) that it reviewed and approved the research in accordance with the criteria listed above; **and**
2. The Secretary (OHRP) must determine that the proposed research falls within one of the categories of permissible research.

Following receipt of the required certification letter from the IRB, OHRP will determine whether it concurs with the IRB's decision to approve the research.

The Institutional Official is responsible for certifying to OHRP that the duties of the IRB have been fulfilled.

Participants Becoming a Prisoner When Research Was Not Reviewed According to Subpart C

If a subject becomes incarcerated while enrolled in a research study that was not reviewed under subpart C and is federally funded the following procedures apply:

1. Confirm that the participant meets the definition of a prisoner.
2. The subject may need to be terminated from the research unless the study is re-reviewed under subpart C.
3. Before terminating the enrollment of the incarcerated participant, the IRB should consider the risks associated with terminating participation in the study.
4. If the participant cannot be terminated for health or safety reasons, then keep the participant enrolled in the study and review the research under Subpart C. If some the requirements of Subpart C cannot be met, but it is in the best interests of the participant to remain in the study, then:
 - a. Keep the participant enrolled and inform OHRP of the decision along with the justification.
 - b. 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.

Research Not Federally Funded

When research is not federally funded, the IRB has equivalent protections and the following procedures apply:

1. Confirm that the participant meets the definition of a prisoner.
2. Decide whether it is in the best interests of the participant to remain in the study or to terminate enrollment.
3. Decide whether it is feasible for the participant to remain in the study.
 - a. If it is in the best interests of the participant to remain in the study, keep the participant in the study and review the research at next meeting of the convened IRB.
4. Temporary Incarceration
 - a. If the temporary incarceration has no effect on the study, then keep the participant enrolled.
 - b. If the temporary incarceration has an impact on the study, then handle according to the above guidance.

Additional Considerations for the Investigator and the IRB Before Approving Research that Involves Prisoners

1. The protocol for contacting incarcerated subjects (hereinafter referred to as the "prisoner protocol") is to demonstrate that any contact with the prisoner will occur in circumstances that provide sufficient privacy and safety.
2. The protocol is to demonstrate that confidentiality will be maximized throughout the process of arranging with prison officials for contact with the incarcerated subject. To the extent possible, the nature of the study, the enrollment criteria, and the study data are not to be disclosed to prison officials, other inmates, or anyone else who does not have a research-related reason to know. The protocol must demonstrate that, to the extent possible, all of the confidentiality protections implemented for non-incarcerated subjects are implemented for incarcerated subjects.
3. The protocol is to include a description of how incarcerated study participants are to be compensated. The system favored by the IRB is one that provides for payment to the prison administration for distribution in accordance with prison policy.
4. If the study involves discussion of sensitive topics such as substance abuse, mental health problems, criminal activities, or sexual histories, the protocol must ensure that a Certificate of Confidentiality is in place. The informed consent must explain, in language comprehensible to the study population, the protections provided by the Certificate of Confidentiality, as well as the exceptions to such protections, such as mandatory or ethical reporting requirements applicable to the researchers.
5. Given the likelihood that a subject may experience severe mental distress shortly following incarceration, the protocol is to explain how the researchers will determine that a subject is competent to participate in the research at the time of re-contact. If the subject is determined

to be incompetent, the prisoner protocol is to ensure that the subject is not re-consented and that the follow-up is not conducted with that subject.

6. The protocol is to consider the risk to incarcerated subjects who participate in research that requires discussion of highly sensitive topics in light of the prisoner's access to psychological counseling. If no follow-up counseling is available, the IRB must weigh this risk against the benefit of completing the follow-up with the incarcerated subject.
7. The protocol is to describe to the extent possible, the provisions in place to assure that the parole board does not consider the prisoner's participation in the research when making parole decisions.

Related Content

- Department of Health and Human Services Regulations
 - 45 CFR 46 Subpart C: Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects
- IRB Policies
 - Convened IRB: Operational Review Procedures
 - Expedited Review
 - Research Involving Department of Defense Funding

COPY

Approval Signatures

Step Description

Approver

Date

Applicability

Boston Children's Hospital- Policies & Procedures