
Yale University Institutional Review Boards

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IRB Policy 320

IRB Review and Approval of the Participation of Prisoners in Research

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Scope

This policy defines standards for IRB approval of federally funded research involving the participation of prisoners. This policy applies to University IRBs that review studies whose participants include individuals who are prisoners at the time of enrollment in a research study or who become prisoners after enrollment and who are actively participating in research procedures or interventions at the time of their incarceration or detention. Research involving participation of prisoners that is not federally funded will be reviewed and overseen using the ethical concepts embedded in the Common Rule (45 CFR Part 46) and the Belmont Report for the protection of vulnerable participants and of prisoner participants.

Policy Statement

The IRB will approve federally funded research involving prisoners only if, in addition to satisfying all other requirements under both the Common Rule and FDA regulations (if applicable), and securing approval from the State of Connecticut Department of Corrections Research Committee, the research meets all the requirements listed in 45 CFR 46, Subpart C, as described below or the IRB approves an exception as described in this policy. Biomedical or behavioral research conducted or supported by the Department of Health and Human Services (DHHS) involving prisoners as subjects will not be approved unless the research is specifically authorized within the Subpart, and appropriate safeguards are in place to protect them as research participants.

Reason for the Policy

Inasmuch as prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and non-coerced decision whether or not to participate as subjects in research, it is the obligation of the IRB to ensure that additional safeguards are employed for the protection of prisoners involved in research activities. These concerns apply whether the research involves individuals who are prisoners at the time of enrollment in the research or who become incarcerated after they become enrolled in the research. In the latter situation, it is unlikely that the initial design of the research and the consent document contemplated the constraints imposed by incarceration; therefore, additional IRB review and considerations are required. (See Prisoner Research Guide 320 GD

1 for additional information concerning safeguards to employ with populations likely to become incarcerated.)

Definitions

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 which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing. In addition, any individual who satisfies the above definition and who is receiving care in a medical treatment setting will be considered a prisoner for purposes of this policy. For purposes of this policy, the definition of prisoner does not include individuals on probation or parole, or supervised by electronic monitoring devices.

Minimal Risk Prisoner Research

Minimal risk, in regard to prisoners, is defined as: 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. It should be noted that “harms,” when referring to prisoners, are specifically described as physical or psychological. The standard minimal risk is not based on the daily life of a healthy prisoner, but refers to a healthy person as an absolute standard based on the daily lives of healthy non-incarcerated individuals.

Policy Sections

0000.1 Special Composition of IRB

When a fully convened IRB reviews a protocol involving prisoners as subjects, the composition of the IRB must satisfy the following requirements of DHHS regulations at 45 CFR 46.304(a) and (b):

- A majority of the IRB (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the IRB.
- 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, except that where a particular research project is reviewed by more than one IRB, only one IRB need satisfy this requirement.
- In the absence of choosing someone who is a prisoner or has been a prisoner, the IRB should choose a prisoner representative who has a close working knowledge, understanding and appreciation of prison conditions from the perspective of the prisoner.

The IRB will notify the Office for Human Research Protections (OHRP) of any change in the IRB roster occasioned by the addition of a prisoner or a prisoner representative, as required by DHHS regulations at 45 CFR 46.103(b)(3). IRBs will be alert to the impact of roster changes on quorum requirements under HHS regulations at 45 CFR 46.108(b). To meet these requirements, the IRB should:

- Notify OHRP of the name and qualifications of the prisoner representative, if the approved IRB roster does not currently reflect this information, and

- Maintain the CV of the prisoner representative serving on the IRB.

For full board review of research involving prisoners as subjects, the convened IRB must meet the special composition requirements of 45 CFR 46.304 for all types of review of the protocol, including initial review, continuing review, review of protocol amendments, and review of reports of unanticipated problems involving risks to subjects and other matters requiring full IRB attention.

0000.2 IRB Findings for Approval

When an IRB is reviewing a DHHS-funded protocol in which a prisoner is a subject, the IRB must make, in addition to other requirements under 45 CFR 46, Subpart A, seven additional findings under 45 CFR 46.305(a), as follows:

(1) The research under review represents one of the categories of research permissible under 45 CFR 46.306(a)(2):

- (i) 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;
- (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;
- (iii) 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) provided that the study may proceed only after the Secretary (through OHRP) 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;
- (iv) research on practices, both innovative and accepted, which 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 (through OHRP) 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
- (v) research conducted under a Secretarial waiver that involves epidemiologic studies meeting the following criteria:
 1. Research in which the sole purposes are (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, and
 2. Where the institution responsible for the conduct of the research certifies to OHRP, acting on behalf of the Secretary, that the IRB approved the research and fulfilled its duties under 45 CFR 46.305(a)(2)–(7) and determined and documented that (i) The research presents no more than minimal risk and no more than inconvenience to the prisoner-subjects, and (ii) Prisoners are not a particular focus of the 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 (note that the State of Connecticut Department of Corrections Research Committee may require more stringent procedures for subject selection);

(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.

Finally, the IRB will ensure that any other appropriate safeguards are considered and in place before finding the research with prisoners approvable.

0000.3 Certification of IRB Findings

For research conducted or supported by DHHS to involve prisoners, two actions must occur:

(1) The institution engaged in the research must certify to the Secretary (through OHRP) that the IRB designated under its assurance of compliance has reviewed and approved the research under 45 CFR 46.305. Yale University, through delegating its institutional authority to the IRB, will certify that it has made the seven required findings. When the Yale IRB, by formal agreement, is relied upon by another institution to conduct its review of human subjects research, the Yale IRB will certify its findings on behalf of that institution to OHRP; and

(2) The Secretary (through OHRP) must determine that the proposed research falls within the above listed categories of research permissible under 45 CFR 46.306(a)(2). DHHS-conducted or –supported research involving prisoners as subjects may not proceed until OHRP issues its approval in writing to Yale on behalf of the Secretary. [See Procedure on Certification of Prisoner Findings]

Note: According to OHRP requirements, research involving prisoners not conducted or supported by DHHS should not be certified to OHRP.

0000.4 Documentation of Findings

The IRB shall prepare and maintain adequate documentation of IRB activities. For the purposes of Subpart C, the IRB activities include making the specific findings required under DHHS regulations at 45 CFR 46.305(a). The documentation of protocol-specific information

justifying each IRB finding required under 45 CFR 46.305(a) will adequately document the IRB activities required under Subpart C.

Special Situations/Exceptions

Additional Considerations when the Participant is on Parole, Probation or Supervised by Electronic Monitoring Devices

While not meeting the definition of prisoner, individuals who are on parole, probation, or are supervised by electronic monitoring devices should be regarded as vulnerable due to their status, particularly in light of the possibility that violating conditions of their restraint could result in their incarceration. The research plan, from recruitment to retention to privacy protections for these individuals, should be carefully designed by the researcher and receive heightened scrutiny from the IRB to ensure that no procedures compromise the safety or status of these participants or otherwise negatively affect their well-being. (See Prisoner Research Guidance 320 GD1 for additional information.)

Permissible Research when the Participant is both a Prisoner and a Minor

When a research participant is both a prisoner and a minor, in addition to 45 CFR 46, Subpart C, the IRB must also consider the special regulatory requirements found under Subpart D that pertain to the involvement of children in research. [See IRB Policy 310, The Participation of Children in Research.] Specific guidance suggests that an adolescent detained in a juvenile detention facility would be considered a prisoner, and Subpart D would also apply. Considerations include vulnerability of the minor, developmental age, and the fact that the rights of the minor's parents to direct the child's activities have been involuntarily subjugated to the State Department of Corrections. Involvement of these individuals in research requires close scrutiny, as a minor who is also a prisoner could be a highly vulnerable subject.

Involvement of Prisoners in Research which is not Biomedical or Behavioral and is not Federally Funded

For projects which do not constitute biomedical or behavioral research, including but not limited to historical research and oral histories, the IRB may permit research that does not conform to the categories listed in 45 CFR 46.306 if all of the following conditions are met:

- The project is not federally funded;
- The majority of the participants are not incarcerated;
- The proposed incarcerated participant is integral to study integrity; and
- The interview questions are unrelated to the proposed participant's status as an incarcerated individual or to reason for their incarceration.

IRB review of such studies will conform to the other requirements of this policy.

Contacts

Subject	Contact	Phone
Recruiting prisoners into biomedical research protocols	Human Investigation Committee	203.785.4688 ysmhic@yale.edu
Recruiting prisoners into social/behavioral research protocols	Human Subjects Committee	203.436.3650 human.subjects@yale.edu
Recruiting prisoners into nursing research protocols	Human Subjects Research Review Committee	203.737.2371 Nursing.yale.edu/Research/ Oversight/

Roles and Responsibilities

[Human Investigation Committee](#)

The HIC I and HIC II serve as the two Institutional Review Boards or IRBs for biomedical human subjects research conducted at Yale University.

[Human Subjects Committee](#)

The HSC is responsible for the review and oversight of social and behavioral research involving human subjects.

[Human Subjects Research Review Committee](#)

The HSRRC serves as the IRB for all research involving human subjects that is conducted by faculty and students at the Yale School of Nursing.

Related Information

Policy 100: IRB Review Policy

Policy 310: Participation of Children in Research

Procedure 320 PR.1: Measures to be Taken When a Current Research Participant Becomes a Prisoner

Procedure 320 PR.2: Institution Certification of Prisoner Findings to OHRP

Guide 320 GD.1: Prisoner Research Guidance

Checklist 320 CH.1: Studies Involving Prisoners

References

45 CFR 46.301, 302, 303, 304, 305, 306.

OHRP Prisoner Frequently Asked Questions: <http://www.hhs.gov/ohrp/prisonerfaq.html>

Julia Gorey, J.D., Division of Policy and Assurances, Office for Human Research Protections (OHRP), e-mail and telephone communication clarifying composition of IRB for full board review, and certification requirement where IAA is in place.