IRB Policy 320 IRB Review and Approval of the Participation of Prisoners in Research

Scope

This policy defines standards for Institutional Review Board (IRB) approval of human 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 detainment.

Policy Statement

The IRB will approve research involving prisoners only if, in addition to satisfying all other requirements under University policy, the Common Rule and Food and Drug Administration (FDA) regulations (if applicable), 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. In addition, compliance with the Department of Justice regulations at 28 CFR §46 and approval from the State of Connecticut Department of Corrections Research Committee are required where applicable. 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, including psychiatric units and hospitals and drug treatment 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

### 320.1 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. This member must be present at the meeting in which prisoner research will be reviewed either in person or via phone or video conference. The prisoner representative shall present his or her review the materials with specific focus on the protection of the rights and welfare of prisoner participants, including the requirements of 45 CFR §46 Subpart C. The prisoner representative may be an alternate member as long as they are serving as a voting member when prisoner research is under review.
- 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.

### 320.2 IRB Findings for Approval

When an IRB is reviewing a 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.

320.3 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.

320.4 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 federal 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. In addition, under Connecticut law, individuals on parole are considered to be under the custody of the Commissioner of Correction until released from parole and therefore are considered to be “prisoners” by the state (CGS 325 Sec. 18-84). Therefore, 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.)

Prohibited Research on Prisoners of War
Research with prisoners of war (POW) is prohibited for any Department of Defense-sponsored research. Investigators should refer to the definition of “prisoner of war” for the particular Department of Defense component supporting the research.

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 or the Department of Children and Families. 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
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 §46) and the Belmont Report for the protection of vulnerable participants and of prisoner participants.
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.

**Bureau of Prisons Projects**

Additional restrictions are required for research within the Federal Bureau of Prisons and these apply to research involving inmates in the custody of the US Attorney General and assigned to the Bureau of Prisons. Inmates at federal prison facilities are subject to Bureau of Prison requirements. In the case of state prison facilities, the PIs must confirm with the prison facility whether there are any federal prisoners in the facility and exclude them from the study.

For research conducted with the Bureau of Prisons note that implementation of Bureau programmatic or operational initiatives made through pilot projects is not considered to be research and hence not subject to IRB purview.

Research that is conducted in the Bureau of Prisons must conform to the requirements of 28 CFR 512 including the following:

- The project must not involve medical experimentation, cosmetic research or pharmaceutical testing.
- The research design must be compatible with both the operation of prison facilities and protection of research participants. The researcher must observe the rules of the institution or office in which the research is conducted.
- Any researcher who is not an employee of the Bureau must sign a statement in which the researcher agrees to adhere to the provisions of 28 CFR 512.
- All research proposals will be reviewed by the Bureau Research Review Board.
- The project must have adequate research design and contribute to the advancement of knowledge about corrections.
- The selection of participants within any one organization must be equitable.
- Incentives may not be offered to help persuade inmate participants to participate. However, soft drinks and snacks to be consumed at the test setting may be offered.
- Reasonable accommodations such as nominal monitory recompense for time and effort may be offered to non-confined research participants who are both 1) no longer in Bureau of Prisons custody and 2) participating in authorized research being conducted by Bureau employees and contractors.
- Researchers that are not employees of the Bureau of Prisons may receive records in a form not individually identifiable only with advance adequate written assurance to the agency that the record will be used as a statistical research or reporting record.
- Except as noted in the consent statement to the participant, the researcher must not provide research information that identifies a participant to any person without that participant’s prior written consent to release the information. For example, research information identifiable to a particular individual cannot be admitted as evidence or used for any purpose in any action, suit, or other judicial, administrative, or legislative proceeding without the written consent of the individual to whom the data pertain.
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- Except for computerized data records maintained at an official Department of Justice site, records that contain non-disclosable information directly traceable to a specific person may not be stored in, or introduced into, an electronic retrieval system.

- If the researcher is conducting a study of special interest to the Office of Research and Evaluation (ORE) but the study is not a joint project involving ORE, the researcher may be asked to provide ORE with the computerized research data, not identifiable to individual participants, accompanied by detailed documentation. These arrangements must be negotiated prior to the beginning of the data collection phase of the project.

- In addition to the requirements for consent in IRB policy 200, the consent form must include the following:
  - Identification of the researchers
  - A description of the anticipated uses of the results of the research
  - A statement that participation is completely voluntary and that the participant may withdraw consent and end participation in the project at any time without penalty or prejudice at which time the inmate will be returned to regular assignment or activity by staff as soon as practicable.
  - A statement regarding the confidentiality of the research information and exceptions to any guarantees of confidentiality required by federal or state law. For example, a researcher may not guarantee confidentiality when the participant indicates intent to commit future criminal conduct or harm him/herself or someone else, or, if the participant is an inmate, indicates intent to leave the facility without authorization.
  - A statement that participation in the research project will have no effect on the inmate participant's release date or parole.

- Researchers are required to have academic preparation or experience in the area of study of the proposed research.

- Proposals must include the following information:
  - A summary statement, which includes:
    - Names and current affiliations of the researchers.
    - Title of the study.
    - Purpose of the study.
    - Location of the study.
    - Methods to be employed.
    - Anticipated results.
    - Duration of the study.
    - Number of participants (staff or inmates) required and amount of time required from each.
    - Indication of risk or discomfort involved as a result of participation.
  - A comprehensive statement, which includes:
    - Review of related literature.
    - Detailed description of the research method.
    - Significance of anticipated results and their contribution to the advancement of knowledge.
    - Specific resources required from the Bureau of Prisons.
    - Description of all possible risks, discomforts, and benefits to individual participants or a class of participants, and a discussion of the likelihood that the risks and discomforts will actually occur.
    - Description of steps taken to minimize any risks.
  - Description of physical or administrative procedures to be followed to:
    - Ensure the security of any individually identifiable data that are being collected for the study.
    - Destroy research records or remove individual identifiers from those records when the research has been completed.
Description of any anticipated effects of the research study on organizational programs and operations.

Relevant research materials such as vitae, endorsements, sample consent statements, questionnaires, and interview schedules.

- Any institutions involved in Yale research involving the Bureau of Prisons must have an active Federalwide Assurance on file with the Office of Human Research Protections.
- Researchers conducting research in the Bureau of Prisons are responsible for the actions of anyone engaged to participate in the research project as an associate, assistant or subcontractor to the researcher.

**Studies Funded by the National Institute of Justice**

For research funded by the National Institute of Justice (NIJ) the following requirements must be met:

- All projects are required to have a privacy certificate approved by the NIJ Human Subjects Protection Officer. Note that under a privacy certificate, researchers are not required to report child abuse unless the participant signs another consent form to allow child abuse reporting.

- All researchers and research staff are required to sign employee confidentiality statements which are to be maintained by the Principal Investigator.

- Research conducted in or in collaboration with the Bureau of Prisons additionally must meet the requirements described above.

- The confidentiality statement on the consent form must state that confidentiality can only be broken if the participant reports immediate harm to participants or others.

**Related Information**

IRB Policy 100: IRB Review Policy

IRB Policy 310: Participation of Children in Research

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

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

320 GD.1: Prisoner Research Guidance

320 CH.1: Studies Involving Prisoners


**Contacts**

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<tr>
<th>Subject</th>
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<th>Phone</th>
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<tbody>
<tr>
<td>Recruiting prisoners into research protocols</td>
<td>Human Investigation Committee or Human Subjects Committee</td>
<td>203.785.4688 <a href="mailto:yshmhc@yale.edu">yshmhc@yale.edu</a> <a href="mailto:human.subjects@yale.edu">human.subjects@yale.edu</a></td>
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**Roles and Responsibilities**

Human Research Protection Program (HRPP)
The Human Research Protection Program is responsible for oversight of human research protection through ongoing education, monitoring, and evaluation of all parties involved in the conduct of human research.

**Human Investigation Committee** (HIC)

The HIC I, HIC II, HIC III and HIC IV serve as the four Institutional Review Boards or IRBs for biomedical human research conducted at Yale University.

**Human Subjects Committee** (HSC)

The HSC serves as the Institutional Review Board for social, behavioral and educational human research at Yale University.

**References**

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

OHRP Prisoner Frequently Asked Questions: [http://answers.hhs.gov/ohrp/categories/1568](http://answers.hhs.gov/ohrp/categories/1568)

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.

**Revision History:**

1/31/2009, 5/5/2010, 9/19/12, 11Dec2017