

Policy II4A-C Participation of Prisoners in Research

Scope

This policy defines standards for University of Nevada, Reno (the University) Institutional Review Board (IRB) approval of 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.

Note: Additional requirements for VA and DoD-Sponsored research involving prisoners are provided separately at the end of this document.

Policy Statement

The IRB will approve research involving prisoners only if, in addition to satisfying all other requirements under both the Common Rule and FDA regulations (if applicable), the research meets all the requirements listed in 45 CFR 46, Subpart C, as described below. Biomedical or behavioral research 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 II4-C GD1 Additional Considerations for Prisoner Research for 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.

Note: "Harms," when referring to prisoners, are specifically described as physical or psychological and that the standard minimal risk for prisoners who are research subjects 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.

II4A-C1 Special Composition of the 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 45CFR 46.304(a) and (b).
- A majority of the IRB (exclusive of prisoner members) shall have no association with the prisons 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.

Note: When a particular research project is reviewed by more than one IRB, only one IRB need satisfy the requirement for at least one IRB member to be a prisoner or prisoner representative.

- The prisoner representative must be a voting member of the IRB.
- The prisoner representative may be listed as an alternative member who becomes a voting member when needed.
- The prisoner representative must review research involving prisoners, focusing on the requirements in 45 CFR 46 Subpart C or equivalent protections.
- The prisoner representative must receive all review materials pertaining to the research (i.e., the same materials provided to the primary reviewer).
- The prisoner representative must be present at a convened meeting when the research involving prisoners is reviewed. If the prisoner representative is not present, research involving prisoners cannot be reviewed or approved.

- The prisoner representative may attend the meeting by phone, video-conference, or webinar, as long as the representative is able to participate in the meeting as if they were present in person at the meeting.
- The prisoner representative must present her or his review either orally or in writing at the convened meeting of the IRB when research involving prisoners is reviewed.
- 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 DHHS 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 DHHS regulations at 45 CFR 46.108(b). To meet these requirements, the IRB must

- notify federal 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 protocol reviews, 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.

II4A-C2 IRB Review of Modifications and Renewals for Prisoner Research

The additional requirements itemized below apply to modifications and renewals for existing protocols for research involving prisoners.

- Modifications may be reviewed using the expedited procedure providing the changes are minor and the review is conducted by the IRB member who is the prison representative (see IRB Policy II2 Review of Research Protocols, procedure II2 PR2 and guidance II2 GD2).
- Modifications involving more than a minor change reviewed by the convened IRB must use the same procedures for initial review including the responsibility of the prisoner representative to review the modification and participate in the meeting (as described in section II4A-C1 above).
- Continuing reviews of research involving prisoners must use the same procedures for initial review including the responsibility of the prisoner representative to review the continuing review materials and participate in the meeting (as described in section II4A-C1 above).

II4A-C3 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, the following findings under 45 CFR 46.305(a):

1. The research under review represents one of the six categories of research permissible under 45 CFR 46.306(a)(2):
 - a. 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;
 - b. 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;
 - c. 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;
 - d. 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
 - e. research conducted under a Secretarial waiver that involves epidemiologic studies meeting the following criteria:
 - i. 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
 - ii. 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 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 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.
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.

Note: All of the above requirements must be addressed.

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

II4A-C4 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) (see II4A-D CH Research with Prisoners).

II4A-C5 Special Situations and Exceptions

II4A-C5a 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. (For more information, see II4A-C GD1 Additional Considerations for Prisoner Research.)

II4A-C5b Prohibited Research on Prisoners of War

For research sponsored by the Department of Defense or conducted at or by researchers in the VA Sierra Nevada Health Care System:

1. Research with prisoners of war is prohibited.
2. Investigators should refer to the definition of “prisoner of war” for the particular Department of Defense component supporting the research.

II4A-C5c 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 Policy II4A-D 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.

II4A-C6 Agency Specific Requirements for Research Involving Prisoners

II4A-C6a VA Research

Research involving prisoners as subjects is not allowed unless a waiver has been granted by the chief research and development officer.

II4A-C6b Department of Defense-Sponsored Research

Additional Department of Defense (DoD) requirements for research involving prisoners are itemized below.

- Research involving prisoners cannot be reviewed by the expedited procedure.
- In addition to allowable categories of research on prisoners in Subpart C, epidemiological research is also allowable when the research
 - describes the prevalence or incidence of a disease by identifying all cases or studies potential risk factor association for a disease,
 - presents no more than minimal risk, and

- presents no more than an inconvenience to the subject.

When a prisoner becomes a subject, if the investigator asserts to the IRB that it is in the best interest of the prisoner-subject to continue to participate in the research while a prisoner, the IRB chair may determine that the prisoner-subject may continue to participate until the convened IRB can review this request to approve a change in the research protocol and until the organizational official and the DoD office of the relevant component review the IRB's approval to change the research protocol. Otherwise, the IRB chair shall require that all research interactions and interventions with the prisoner-subject (including obtaining identifiable private information) cease until the convened IRB can review this request to approve a change in the research protocol.

The convened IRB, upon receipt of notification that a previously enrolled human subject has become a prisoner, shall promptly re-review the research protocol to ensure that the rights and wellbeing of the human subject, now a prisoner, are not in jeopardy. The IRB will consult with the prisoner representative and said representative will review the request to modify the protocol.

The convened IRB may approve a change in the study to allow the prisoner-subject to continue to participate in the research if the following conditions are met:

- the prisoner-subject can continue to participate voluntarily and fully-informed (i.e., provides informed consent),
- the prisoner subject is capable of meeting the research protocol requirements,
- the terms of the prisoner-subject's confinement does not inhibit the ethical conduct of the research, and
- there are no other significant issues preventing the research involving human subjects from continuing as approved.

Note: This approval is limited to the individual prisoner-subject and does not allow recruitment of prisoners as subjects.

The DoD prohibits research involving a detainee as a human subject. This prohibition does apply to research involving investigational drugs and devices when the same products would be offered to US military personnel in the same location for the same condition.