

DEPARTMENT: INSTITUTIONAL REVIEW BOARD
POLICY NUMBER: 026
SECTION: GENERAL IRB POLICIES
REVIEW RESPONSIBILITY: IRB
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SUBJECT: Special Categories of Research: Prisoners as Research Subjects.

1. The special vulnerability of prisoners makes consideration of involving them as research subjects particularly important. Prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research. To safeguard their interests and to protect them from harm, special ethical and regulatory considerations apply for reviewing research involving prisoners. Therefore, if a protocol involves the use of prisoners as subjects, both the general IRB policies apply and the special requirements outlined in this policy apply. Note: the IRB may approve research involving prisoners only if these special provisions are met.
2. The federal regulations provide a unique definition of “Minimal Risk” as it pertains to prisoners as research subjects, and such definition differs from the definition of minimal risk in the Common Rule. The definition for prisoners requires reference to physical or psychological harm, and reads as follows: “Minimal Risk” 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.
3. Definition of Prisoner. As used in this policy, “Prisoner” means 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.
4. This Policy applies to all research involving prisoners as subjects when one of more of the following apply:
 - The research is sponsored by Florida State University; or
 - The research is conducted by or under the direction of any employee or agent of FSU in connection with his or her institutional responsibilities; or
 - The research is conducted by or under the direction of any employee or agent of FSU using any property or facility of FSU; or
 - The research involves the use of FSU’s non-public information to identify or contact human research subjects or prospective subjects.

5. This Policy applies whenever any human subject in a research protocol becomes a prisoner at any time during the protocol, even after the research has commenced. This is necessary because it is unlikely that review of the research and the consent document contemplated the constraints imposed by the future incarceration of the subject.
 - If a subject becomes a prisoner after enrollment in research, the Investigator is responsible for reporting in writing this situation to the IRB immediately.
 - Promptly upon receiving the Investigator's notice or otherwise becoming aware of the prisoner status of a subject, the IRB should review the protocol again with a prisoner representative to the IRB. The Committee should take special consideration of the conditions of being a prisoner. The IRB should confirm that, when appropriate, the informed consent process includes information regarding when subsequent incarceration may result in termination of the subject's participation by the Investigator without regard to the subject's consent.
 - Upon this review, the IRB can either approve the involvement of the prisoner subject in the research in accordance with this policy or determine that this subject must be withdrawn from the research.

6. Composition of the IRB When Prisoners are Involved. If an IRB regularly reviews research that involves prisoners consideration shall be given to the inclusion of one or more individuals who are knowledgeable and experienced in working with these subjects.
 - a) To review a protocol involving prisoners as subjects, a majority of the IRB (exclusive of prisoner members) shall have no association with the prison involved, apart from their membership on the IRB, and at least one member of the IRB shall 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.
 - b) If a prisoner representative ("PR") is selected to serve on the IRB Committee, the person must have a close working knowledge of prison conditions and the life of a prisoner. Suitable individuals could include present or former prisoners, prison chaplains, prison psychologists, prison social workers, or other prison service providers; persons who have conducted advocacy for the rights of prisoners; or any individuals who are qualified to represent the rights and welfare of prisoners by virtue of appropriate background and experience.
 - c) The IRB must meet the special composition requirements for all types of review of the protocol – initial review, continuing review, protocol amendments, and reports of unanticipated problems involving risks to subjects.

- d) The IRB must notify OHRP of any change in the IRB roster occasioned by the addition of a prisoner or a prisoner representative.
7. Specific Findings of IRB Required to Approve Research. When reviewing a protocol in which a prisoner is a subject, the IRB must make additional findings as follows:
- a) The research under review represents one of the follows categories of research:
- 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;
 - A 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 (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); 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;
- b) 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;
- c) The risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;
- d) 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 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;
- e) The information is presented in language which is understandable to the subject population;
- f) 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

- g) 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.
- 8. Permitted Research Involving Prisoners. For research conducted or supported by HHS to involve prisoners, two actions must occur. First, the IRB must certify to OHRP that it has reviewed and approved the research under the federal regulations and second, that OHRP must determine that the proposed research falls within one of the categories of permissible research as described in Paragraph 7(a) above.
 - a) If an Investigator wishes to engage in non-HHS supported research, certification is not required. However, the IRB should apply the standards of this policy and the federal regulations in reviewing the research.
 - b) Should the research involve conditions particularly affecting prisoners as a class, or not satisfy the stipulations at Paragraph 7(a) above, the research should proceed only after the IRB has consulted with appropriate experts, as determined by the IRB.
 - c) The IRB certification to OHRP should consist of a certification letter stating that the IRB has been constituted properly according to federal regulation, that the IRB considered and made the required seven (7) findings set forth in 45 CFR 46.305, and that the IRB "finds that category (insert which category applies) of 45 CFR 46.306 permits this research to go forward with prisoners as human subjects." The certification letter should also provide a brief description of this research sufficient to allow OHRP to determine whether or not to concur with the IRB, and whether OHRP needs to consult with appropriate experts and publish a Federal Register Notice. The IRB Office should retain a copy of this letter.
- 9. Prisoners Who Are Minors. When a prisoner is also a minor (i.e. an adolescent detained in a juvenile detention facility is a prisoner), then the Policy regarding Children in Research will also apply.
- 10. Expedited Review of Research Involving Prisoners Not Allowed. The full committee must review research involving prisoners as human subjects.
- 11. Exemption from Review of Research Involving Prisoners Not Allowed. Research that would otherwise be exempt from the requirement that it receive IRB approval is not exempt when the research involves prisoners.
- 12. Documentation. When approving a protocol involving prisoners, the minutes must document that the Committee made the findings required above. The IRB must classify research involving prisoners into one of the seven categories described within Paragraph (7) above and document their discussions of the risks and benefits of the research study.

13. Federal Bureau of Prisons. The Federal Bureau of Prisons places special restrictions on research that takes place within the Bureau. The IRB should review the regulations at 28 CFR Part 512 when considering such research.