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INSTITUTIONAL REVIEW BOARD  
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**Supplementary Application for Research Involving Prisoners**

Name of Investigator:

IRB Study #:

Title of Protocol:

Date of Submission:

**Please complete this form only if applicable to your research study.**

Prisoners are considered a vulnerable research population because they are in a restrictive, institutional environment that provides little opportunity for making choices, earning money, communicating with outsiders, or obtaining medical care. Because their autonomy is limited, prisoners may only participate in certain categories of research, and special precautions are necessary to assure that their consent to participate is informed and voluntary. Additionally, in order to legally review an application that involves prisoner research, a qualified prisoner representative must be a voting member of the IRB.

Research permitted with prisoners must fall into one of the following categories. Please check the one that describes your proposal.

1. The research in categories (i) and (ii) must be minimal risk research <sup>1</sup> .	
<input type="checkbox"/>	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.
<input type="checkbox"/>	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.
2. The research in categories (iii) and (iv) may require OHRP to have the research reviewed by appropriate experts and may require a notice of intent to approve the research published in the <u>Federal Register</u> .	
<input type="checkbox"/>	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 has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the <i>Federal Register</i> , of his intent to approve such research.
<input type="checkbox"/>	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 has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the <i>Federal Register</i> , of the intent to approve such research.

<sup>1</sup> Definition of Minimal Risk in Prisoner Subpart 45 CFR 46.303(d): Minimal risk is 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**.

**When an IRB is reviewing a protocol in which a prisoner is a subject, the IRB must make seven additional findings under 45 CFR 46.305 as listed below.**

1. The research under review represents one of the categories of research permissible under Section 46.306(a)(2).
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 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 that 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.

**Frequently asked questions pertaining to prisoner research.**

1. Does Subpart C apply only where the research targets prisoners as subjects/participants?  
Answer: No. Subpart C applies whenever any human subject/participant in a research protocol subject to 45 CFR Part 46 becomes a prisoner at any time during the protocol.
2. What should an investigator do if a subject/participant becomes a prisoner after enrollment in research?  
Answer: The investigator should report this situation to the IRB immediately.
3. What does the IRB do when a human subject/participant becomes a prisoner after enrollment?  
Answer: At the earliest opportunity, the IRB should review the protocol again with a prisoner representative on the IRB and an eye to the special conditions of being a prisoner. The IRB can either (a) approve the involvement of the prisoner-subject in the research in accordance with Subpart C or (b) determine that this subject must be withdrawn from the research. Note that 46.116 requires, when appropriate, that the informed consent process include information on anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.
4. Is an adolescent (e.g., age 14) detained in a juvenile detention facility a prisoner?  
Answer: Yes. In addition to Subpart C, most likely Subpart D would also apply.
5. Can research involving prisoners be expedited?  
Answer: OHRP recommends that the full IRB review research involving prisoners as human subjects.
6. Do the exemptions apply to research involving prisoners?  
Answer: The exemptions at 45 CFR 46.101(b) do not apply to research involving prisoners. See 45 CFR 46.101(i).