

## Summary Table for 45 CFR 46, Subpart C Reviewing Research Involving Prisoners

For all biomedical and behavioral research involving prisoners<sup>2</sup> as subjects. Inasmuch as prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and un-coerced decision whether or not to participate as subjects in research, it is the purpose of this subpart to provide additional safeguards for the protection of prisoners involved in activities to which this subpart is applicable. As required by OHRP the final decision of the risk category will be established at the IRB meeting and reflected in the letters and minutes.

<b>45CFR46</b>	<b>Category</b>	<b>Explanation</b>
46.304	<b>Composition of Institutional Review Boards where prisoners are involved.</b>	<ul style="list-style-type: none"> <li>a. A majority of the Board (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the Board.</li> <li>b. At least one member of the Board 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 Board only one Board need satisfy this requirement.</li> </ul>
46.305	<p><b>Additional duties of the Institutional Review Boards where prisoners are involved.</b></p> <p>(a) In addition to all other responsibilities prescribed for Institutional Review Boards under this part, the Board shall review research covered by this subpart and approve such research only if it finds that:</p>	<ul style="list-style-type: none"> <li>1. The research under review represents one of the categories of research permissible under <a href="#">§46.306</a> (a)(2);</li> <li>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;</li> <li>3. The risks involved in the research are commensurate with risks that would be accepted by non prisoner volunteers;</li> <li>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 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;</li> <li>5. The information is presented in language which is understandable to the subject population;</li> <li>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; <b>AND</b></li> </ul>

		7. Where the Board 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.
46.305	<b>Additional duties of the Institutional Review Boards where prisoners are involved.</b>	<p>b. The Board shall carry out such other duties as may be assigned by the Secretary.</p> <p>The institution shall certify to the Secretary, in such form and manner as the Secretary may require, that the duties of the Board under this section have been fulfilled.</p>
46.306	<b>Permitted research-involving prisoners.</b>	<p>a. Biomedical or behavioral research conducted or supported by DHHS may involve prisoners as subjects only if:</p> <ol style="list-style-type: none"> <li>1. The institution responsible for the conduct of the research has certified to the Secretary that the Institutional Review Board has approved the research under <a href="#">§46.305</a> of this subpart; and</li> <li>2. In the judgment of the Secretary the proposed research involves solely the following: <ol style="list-style-type: none"> <li>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;</li> <li>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;</li> <li>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 has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the <b>Federal Register</b>, of his intent to approve such research; <b>OR</b></li> <li>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 has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the <b>Federal Register</b>, of the intent to approve such research.</li> </ol> </li> </ol> <p>b. Except as provided in paragraph (a) of this section, biomedical or behavioral research conducted or supported by DHHS shall not involve prisoners as subjects.</p>

<sup>1</sup> “Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom authority has been delegated,” 45CFR46.303

<sup>2</sup> “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,” 45CFR46.303

<sup>3</sup> “Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests,” 45CFR46.102