**Subpart C**

**§46.302 Purpose.**

Inasmuch as 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, 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.

 **§46.305 Additional duties of the Institutional Review Boards where prisoners are involved.**

 (a) In addition to all other responsibilities prescribed for Institutional Review Boards under [this part](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#part46), the Board shall review research covered by this subpart and approve such research only if it finds that:

 (1) The research under review represents one of the categories of research permissible under [§46.306(a)(2)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.306%28a%29%282%29);

 (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 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;

 (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 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.

 (b) The Board shall carry out such other duties as may be assigned by the Secretary.

 (c) 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.

**§46.306 Permitted research involving prisoners.**

 (a) Biomedical or behavioral research conducted or supported by DHHS may involve prisoners as subjects only if:

 (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 [§46.305](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.305) of this subpart; and

 (2) In the judgment of the Secretary the proposed research involves solely the following:

 (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 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

 (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 FEDERAL REGISTER, of the intent to approve such research.

 (b) Except as provided in [paragraph (a)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.306%28a%29) of this section, biomedical or behavioral research conducted or supported by DHHS shall not involve prisoners as subjects.

**§46.409 Wards.**

 (a) Children who are wards of the state or any other agency, institution, or entity can be included in research approved under [§46.406](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.406) or [§46.407](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.407) only if such research is:

 (1) Related to their status as wards; or

 (2) Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

 (b) If the research is approved under [paragraph (a)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.409%28a%29) of this section, the IRB shall require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.