

## Appendix C: PRISONERS

Under 45 CFR 46.303, "Prisoner" means any individual involuntarily confined or detained in a penal institution. Individuals are prisoners if they are in any kind of penal institution, such as a prison, jail, juvenile offender facility, or court-ordered substance abuse facilities, and their ability to leave the institution is restricted. Prisoners may be convicted felons, or may be untried persons who are detained pending judicial action, for example, arraignment, or trial.

1. Research involving prisoners is permissible only if the research involves one or more of four permissible categories, or if the research meets the criteria described in an HHS Secretarial waiver that applies to certain epidemiological research. Please indicate under which category your research falls:
  - \_\_\_\_\_ The study of the possible causes, effects, and processes of incarceration, and of criminal behavior
  - \_\_\_\_\_ The study of prisons as institutional structures or of prisoners as incarcerated persons
  - \_\_\_\_\_ Research on conditions particularly affecting prisoners as a class; vaccine trials and other research on hepatitis and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults. Research in this category funded by HHS may proceed only after the HHS Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and has published notice in the Federal Register of his or her intent to approve the research
  - \_\_\_\_\_ Research on practices, either innovative or accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In this category, if the IRB-approved proposal is a study in which some prisoners will be assigned to a control group and these prisoners may not benefit from their participation in research, such research, if funded by HHS, may proceed only after the HHS Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and has published notice in the Federal Register of his or her intent to approve the research.
2. List any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, and quality of food, amenities and opportunity for earnings in the prison. They must not be of such a magnitude that his or her ability to weigh the risks of the research against the value of receiving such advantages in the limited-choice prison environment is impaired.
3. Describe how the risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers.

4. Demonstrate that 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 the IRB with written justification for following some other procedures, control subjects must be selected randomly from the group of available prisoners that meet the characteristics needed for that particular research proposal.
  
5. Confirm information is presented in language that is understandable to the subject population.
  
6. Provide adequate assurance 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. Should there be a need for follow-up examination or care of participants after the end of their participation, adequate provision must be made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.