

Investigator Checklist for Studies Involving Prisoners

Protocol Title: _____

This checklist is designed to assist the IRB in determining if your research fulfills all the requirements of the federal regulations as outlined in 45 CFR 46 Subpart C for inclusion of prisoners as research subjects. Special risk/benefit determination must be discussed and documented by the IRB, in order for prisoners to be included as research subjects.

Definition of prisoner for the application of special protections

Prisoners means any individual involuntarily confined or detained in a penal institution, including individuals detained in other facilities which provide alternatives to criminal prosecution or incarceration, and individuals detained arraignment, trial or sentencing – 45 CFR 46.303(c)

In order to satisfactorily complete a protocol that includes the use of prisoners as participants in a research study, the investigator must determine which of the following categories applies to the research study proposed.

I. Please designate the category that you feel describes the involvement of prisoners in this research activity.

_____ (A) Study of the possible causes, effects, and processes of incarceration, and criminal behavior provided that the study presents no more than minimal risk and no more than inconvenience to subjects.

_____ (B) 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.

_____ (C) Research on conditions particular affecting prisoners as a class (e.g., vaccine trials and other research on hepatitis which is much more prevalent in prisoners 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/her intent to approve such research.

_____ (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 Federal Register, of his/her intent to approve such research.

II. In addition, in order for your protocol to be complete please determine that all of the conditions below apply. Initial each condition to indicate your determination that the condition is met.

_____ (1) the research under review represents one of the categories of research permissible under on of the categories above;

_____ (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 the 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 you provide 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 participant 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 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.

Principal Investigator

Date

Reminder: If the prisoners are minors, all the special protections identified for children are required.