

Date:
CPHS#:

**OPHS WORKSHEET - 45 CFR 46.305
RESEARCH INVOLVING PRISONERS**

I. Criteria for Approval of Research involving prisoners – If prisoners will participate in the research, or subjects may reasonably be expected to become incarcerated at some time point during the course of the study, the Committee for Protection of Human Subjects may approve such research provided that it finds that all of the conditions below are met:

- A. The research under review represents one of the permissible categories of research as described in section II below.

Protocol-specific comments:

- B. Any possible advantages accruing to the prisoner through participation in the research, when compared to the general living conditions, medical care, quality of food, amenities, and opportunity for earnings in prison, are not of such a magnitude that the prisoner's ability to weigh the risks and benefits of the research in the limited-choice environment of the prison is impaired.

Protocol-specific comments:

- C. The risks involved in the research are commensurate with risks that would be accepted by non-prison volunteers.

Protocol-specific comments:

- D. Selection procedures within the prison are fair to all prisoners and immune from arbitrary intervention by prison authority or prisoners. Unless the investigator provides the Committee with justification in writing for following some other procedures, control subjects must be selected randomly from the group of eligible prisoners for the research project.

Protocol-specific comments:

- E. Any information given to subjects is presented in language that is appropriate for the subject population.

Protocol-specific comments:

- F. Adequate assurance exists that parole board(s) 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/her parole.

Protocol-specific comments:

- G. Where the Committee finds there is a need for follow-up examination or care of subjects after the end of their participation in the research, adequate provision has been made for such examination or care, taking into account the varying lengths of prisoner sentences, and for informing subjects of this fact.

Protocol-specific comments:

II. Permissible Categories of research involving prisoners – Research involving prisoners is permissible only if the research involves one or more of four permissible categories, or if the research meets the criteria for a Department of Health and Human Services (DHHS) Secretarial waiver that applies to certain epidemiological research ([68 FR 36929](#), June 20, 2003) as described below (*check all that apply*):

1. The study of the possible causes, effects, and processes of incarceration, and of criminal behavior. Research in this category is permissible only if the study presents no more than *minimal risk*¹, and no more than inconvenience to the subjects.
2. The study of prisons as institutional structures or of prisoners as incarcerated persons. Research in this category is permissible only if the study presents no more than *minimal risk*, and no more than inconvenience to the subjects.
3. Research on conditions particularly affecting prisoners as a class. Examples of such research include 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. Research in this category may proceed only after the 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.
4. 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 may proceed only after the 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. *Control groups which may not benefit from research* include a control group receiving standard of care that the prisoners would otherwise receive, services as usual, or a placebo.
5. The DHHS Secretarial waiver for certain epidemiological research conducted or supported by DHHS functions as a fifth category of permissible research. The criteria for this category are that the research must have as its sole purpose (i) to describe the prevalence or incidence of a disease by identifying all cases, or (ii) to study potential risk factor associations for a disease. CPHS must certify to OHRP that an appropriately constituted committee has reviewed the protocol and found that it meets the criteria for approval of research involving prisoners.

¹ The definition of minimal risk in federal regulations is different for prisoners than for other subject populations. *Minimal risk for prisoners* is defined as “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.”