

## Research Involving Prisoners

Prisoners are a special group of research participants, classified as a “vulnerable population” and protected under the [Common Rule 45 CFR 46 Subpart C](#). “Prisoner” means any individual involuntarily confined or detained in a penal institution, individuals detained in other facilities by virtue of statutes or commitment procedures that provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing. Individuals are prisoners if they are in any kind of penal institution, such as a prison, jail, or juvenile offender facility, 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.

Additionally, the UCA IRB includes in this vulnerable population any individual on parole or under ongoing legal supervision, such that his/her capacity to freely consent or voluntarily could be influenced (or perceived by the individual to be influenced) by figures of authority or supervision.

***All research protocols involving individuals described above must be reviewed by the fully convened board at one of its monthly meetings.***

## **Permitted Behavioral or Biomedical Research Involving Prisoners (45 CFR 46.306)**

1. 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.
2. 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.
3. Research on conditions particularly affecting prisoners as a class (e.g., vaccine trials and other research on hepatitis, more prevalent in prisons; 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 (HHS) 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 [46.306(2)(iii)].
4. 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 [46.306(2)(iv)].

5. Epidemiological Research – defined as “public health research that focuses on a particular condition or disease in order to (i) describe its prevalence or incidence by identifying all cases, including prisoner cases, or (ii) study potential risk factor associations, where the human subjects may include prisoners in the study population but not exclusively as a target group” [68 FR36929, June 20, 2003], provided that the study presents no more than minimal risk and no more than inconvenience to the subjects.

## IRB Requirements

Federal regulations require that the majority of members of the IRB have no association with the prison(s) involved, except for duties related to approving and overseeing research protocols. However, at least one member of the Board must be a prisoner, or a prisoner representative with appropriate background to serve in such capacity, except in the event that a research protocol is reviewed by more than one Board, and another Board satisfies this requirement. (45 CFR 46.304)

Additionally, to approve research involving prisoners, the IRB must determine that:

1. 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 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;
2. The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;
3. 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;
4. The information is presented in language understandable to the subject population;
5. 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
6. If the need exists for follow-up examination or care of participants after the end of their participation, the researcher has made adequate provision for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.