# Conducting Research Involving Prisoners

“Prisoner” is defined to include any individual involuntarily confined in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing. Persons receiving care in a medical treatment setting, who are also “prisoners” as defined above, can be considered for enrollment in research only as permitted for other prisoners as subjects.

## Categories of Research

Only the following kinds of research may involve prisoners as research subjects [45 CFR 46.306]:

* Studies (involving no more than minimal risk or inconvenience) of the possible causes, effects, and processes of incarceration and criminal behavior.
* Studies (involving no more than minimal risk or inconvenience) of prisons as institutional structures or of prisoners as incarcerated persons;
* Research on particular conditions affecting prisoners as a class (for example, research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults)
* Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the prisoner subject’s health or well-being. If such research involves placebo control groups, who may not benefit from the research, and the research is federally funded, the research may only proceed if the Secretary of Health and Human Services approves it. If such research is not federally funded, the research may proceed only if the IRB has consulted with appropriate experts, as determined by the IRB.

When the IRB reviews studies involving prisoners, the IRB pays particular attention to:

* the prisoners’ ability to freely consent to participation without coercion
* the level of compensation
* whether confidentiality of participation and data will be maintained in the prison.

The IRB finds and documents in the minutes or records, the following additional safeguards:

* Any possible advantages accruing to a prisoner through his/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 magnitude that his/her ability to weigh the risks and benefits of the research is impaired; and
* The risks involved in the research are commensurate with the risks that would be accepted by non-prisoner volunteers; and
* Selection procedures of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Control subjects are selected randomly from the groups of available prisoners who meet the characteristics needed for that particular research project; and
* The consent form language is understandable to the subject population; and
* Adequate assurances exist that parole boards will not take into account a prisoner’s participation in the research in making decisions regarding parole, and the prisoner is clearly informed in advance that participation in the research will have no effect on his/her parole; and
* Where the IRB finds that 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 and for informing participants of this fact.

## Waiver of Epidemiology Research

The Secretary of DHHS has waived the applicability of 45 CFR 46.305(a)(1) and 46.306 (a)(2) for certain research conducted or supported by DHHS that involves epidemiologic studies that meet the following criteria:

* Sole purposes of the research are:
  + to describe the prevalence or incidence of a disease by identifying all cases or, or
  + to describe potential risk factor associations for a disease, and
* where the IRB has approved the research and fulfilled its duties under 45 CFR 46.3­5(a)(2)-(7) and determined and documented that:
  + the research presents no more than minimal risk and not more than inconvenience to the prisoner subjects, and
  + prisoners are not a particular focus of the research.

The waiver would allow the conduct of minimal risk research that does not fall within the categories set out in 45 CFR 46(a)(2). The range of studies to which the waiver would apply includes epidemiological research related to chronic diseases, injuries, and environmental health.

In order for a study to be approved under this waiver, the IRB will need to ensure that, among other things, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of the data.

Principal Investigators who plan to include prisoners in studies should contact the IRB office for assistance prior to submitting the protocol for IRB review.