DEFINITION OF “PRISONER” FOR THE APPLICATION OF SPECIAL PROTECTIONS

Prisoner 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 pending arraignment, trial, or sentencing.--- 45 CFR 46.303(c)

PART A

Biomedical or behavioral research conducted or supported by DHHS may involve prisoners as subjects only if it qualifies in one of the four categories below:

1. It is a 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. It is 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;

3. It is research on conditions particularly affecting prisoners as a class (for example, 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) provided that the study may proceed only after the Secretary of DHHS has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of his intent to approve such research; or

4. It is 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, and if the study is DHHS-funded research, the study may proceed only after the Secretary of DHHS 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.

To which of the four categories does this study conform? __________
PART B

This research is permissible only if each condition below has been met:

___ 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 the 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.

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

___ 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.

___ The information is presented in language which is understandable to the subject population.

___ 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 will be clearly informed in advance that participation in the research will have no effect on his or her parole;

___ Where the board 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, taking into account the varying lengths of individual prisoner's sentences, and for informing participants of this fact.

___ All above conditions have been met. This study has been certified by the Institutional Official to the DHHS Secretary (if DHHS funded) as having been approved by the IRB under Section 46.305.

___ The Secretary of DHHS has approved the study (if DHHS-funded). The IRB has taken steps to fulfill any additional duties assigned by the Secretary.

☐ The research may be initiated.

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