**Supplement I**

**RESEARCH INVOLVING PRISONERS AS SUBJECTS**

Indicate your responses below and explain your selections in the protocol. Do not provide details in this document.

# Prisoners as Subjects

45 CFR 46.303 Definitions (c) *Prisoner* means any individual involuntarily confined or detained 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.

## The subjects in this study include (select all that apply):

\_\_ Individuals involuntarily confined or detained in a penal institution.

\_\_ Individuals detained in other facilities by virtue of statutes or commitment procedures, which provide alternatives to criminal prosecution or incarceration in a penal institution.

\_\_ Individuals detained pending arraignment, trial, or sentencing.

\_\_ Other individuals involuntarily detained under a criminal or civil statute.

## Specify in the protocol where the prisoners are located.

* 1. Do you have permission from the facility and the appropriate authorities? (Attach all documentation to the application) \_\_ Yes \_\_ No

## Are any of the subjects in this research minors in the jurisdiction where the research is taking place? \_\_ Yes \_\_ No (*If yes, complete IRB Supplement H*)

# Allowable Risk/Benefit Categories

Check the category below that best represents the nature of the research and the degree of risk and benefit to which the prisoners in this study will be exposed.

**Note:** The definition of minimal risk for prisoners is slightly different from the definition for other subjects. The definition of minimal risk for research involving prisoners given in 46.303(d), is as follows:

Minimal risk is 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.

Select the appropriate risk/benefit assessment below and provide a rationale for the assessment in the protocol to support your selection.

\_\_ **Category 1- 45 CFR 46.306 (a) (2) (i):** The study of the possible causes, effects, and processes of incarceration, and of criminal behavior, where the study presents no more than minimal risk and no more than inconvenience to the subjects

\_\_ **Category 2- 45 CFR 46.306 (a) (2) (ii):** The study of prisons as institutional structures or of prisoners as incarcerated persons, where the study presents no more than minimal risk and no more than inconvenience to the subjects.

\_\_ **Category 3- 45 CFR 46.306 (a) (2) (iii):** The study of conditions particularly affecting prisoners as a class (for example, research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults).  *(Additional procedures are required for approval. Contact the OHSRP for more information.)*

\_\_ **Category 4- 45 CFR 46.306 (a) (2) (iv**): The study of practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject.  *(Additional procedures are required for approval. Contact the OHSRP for more information.)*

## Does the study in Category 4 involve a control group, which will not receive a benefit from being in the study? \_\_ Yes \_\_ No *(If yes, additional procedures are required for approval. Contact the OHSRP for more information.)*

# Additional Criteria

## a. Are there 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? \_\_ Yes \_\_ No

## Are the risks involved in the research commensurate with risks that would be accepted by non-prisoner volunteers? \_\_ Yes \_\_ No

## Are the procedures for the selection of subjects within the prison fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners? \_\_ Yes \_\_ No

## Is the information presented in language that is understandable to the subject population? \_\_ Yes \_\_ No

## Does adequate assurance exist that a parole Board 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? \_\_ Yes \_\_ No *(Explain the rationale for this in the protocol and the consent)*

## If there may be a need for follow-up examination or care of subjects 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 subjects of this fact? \_\_ Yes \_\_ No