

IRB APPENDIX L - PRISONERS

REV. MARCH 2015

OFFICE OF
RESEARCH INTEGRITY

Complete this form to request inclusion of prisoners in the proposed research. The inclusion of prisoners as participants in research requires that the investigator comply with the additional protections provided in [45 CFR 46 Subpart C](#).

Prisoner - An individual involuntarily confined or detained in a penal institution (e.g., prison, jail, or juvenile offender facility), with restricted ability to leave the 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 that provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

The requirements of 45 CFR 46 Subpart C also apply when a participant becomes a prisoner during the research.

For more information see [45 CFR 46 Subpart C](#).

Principal Investigator:

Protocol Short Title:

1. Indicate the category(ies) that best describes the involvement of prisoners in the research:

- This research will examine the possible causes, effects, or processes of incarceration and/or criminal behavior, provided the study presents no more than minimal risk or inconvenience to the participants.
 - This research will examine prisons as institutional structures or prisoners as incarcerated persons, provided the study presents no more than minimal risk or inconvenience to the participants.
 - This research will examine a condition(s) particularly affecting prisoners as a class of people (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).
 - This research will examine practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the participant.
- This research is an epidemiologic study
- (1) to describe the prevalence or incidence of a disease by identifying all cases, or
 - (2) to examine potential risk factor associations for a disease, provided the study presents no more than minimal risk or inconvenience to the participants and prisoners are not a particular focus of the research.

2. Provide the name, type of facility, and location of each local, state, or federal facility to be used.

3. Describe the possible advantages to participating prisoners (i.e., compared to the general living conditions, medical care, quality of food, amenities, and opportunity for earnings in the prison).

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4. Describe any additional steps that will be taken to avoid undue influence (i.e., considering the limited choice environment of the prison).

5. Explain how the risks involved in the research are similar to risks that would be accepted by non-prisoner volunteers.

6. Prisoner Selection

- a. Explain how prisoners will be selected for the study and/or assigned to treatment groups.

The selection of participants within the prison and procedures for assignment to various groups within the research (e.g., experimental vs. control groups) should be designed to be fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners.

- b. Describe safeguards in place to provide assurances that parole boards will not take into account a prisoner's participation in the research when making decisions regarding parole.

Prisoners must be clearly informed in advance that participation in the research will have no effect on their parole.

7. Describe follow-up examinations or care of participants to be provided after their participation has ended (including frequency and duration they will be available), as applicable, taking into account the varying lengths of individual prisoners' sentences.