

IRB Number:	
Protocol Name:	
Investigator:	
<p>The purpose of this checklist is to provide support for IRB members or the Designated Reviewer. Return completed checklist to IRB manager. Please refer to IRB SOP 504, Research with Prisoners.</p>	
<p>The research must meet one of the following two sets of criteria</p>	
<p>1 Non-DHHS-Regulated Research Where a Subject Becomes Incarcerated (Check if "Yes". All must be checked.)</p>	
<input type="checkbox"/>	The research is NOT conducted or funded by DHHS
<input type="checkbox"/>	The subject was not incarcerated at the time of enrollment and subsequent incarceration was unexpected.
<input type="checkbox"/>	The incarceration does not put the rights and wellbeing of the subject in jeopardy.
<input type="checkbox"/>	The prisoner representative has been consulted.
<input type="checkbox"/>	The terms of the subject's confinement do not inhibit the ethical conduct of the research.
<input type="checkbox"/>	There are no other significant issues preventing the research from continuing as approved.
<input type="checkbox"/>	This approval is limited to the individual subject and does not allow recruitment of prisoners.
<input type="checkbox"/>	One of the following is true: (check all that are true)
<input type="checkbox"/>	The subject will be at increased risk of harm if withdrawn from the research
<input type="checkbox"/>	The research presents no more than minimal risk and no more than inconvenience to the subjects.
<p>2 Research Involving Prisoners as Subjectsⁱ (Check if "Yes". All must be checked.)</p>	
<input type="checkbox"/>	<p>The research under review represents one of the following categories of research: (At least one must be checked.)</p> <p><input type="checkbox"/> 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 inconveniences to the subjects.</p> <p><input type="checkbox"/> 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.</p> <p><input type="checkbox"/> 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.)ⁱⁱ</p> <p><input type="checkbox"/> Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject where one of the following is true: (one box must be checked)</p> <p style="padding-left: 20px;"><input type="checkbox"/> All groups may benefit from the research</p> <p style="padding-left: 20px;"><input type="checkbox"/> Prisoners are assigned to control groups which may not benefit from the research.ⁱⁱⁱ</p> <p><input type="checkbox"/> Epidemiologic studies in which the sole purpose is to describe the prevalence or incidence of a disease by identifying all cases or to study the potential risk factor associations for a disease, the research presents no more than minimal risk and no more than inconvenience to the subjects, and prisoners are not a particular focus of the research.</p>
<input type="checkbox"/>	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.
<input type="checkbox"/>	The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers.
<input type="checkbox"/>	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.
<input type="checkbox"/>	The information is presented in a language which is understandable by the subject population.



Institutional Review Board
Checklist: Prisoners

NUMBER HRP-415 Effective date: 10/5/2020

Table with 2 columns: checkbox, text description. Contains 5 rows of checklist items regarding parole board decisions, follow-up care, prisoner representative review, and expedited review procedures.

i If the research is DHHS-regulated, the research may proceed only after the institution has certified to OHRP that the duties of the Board under this section have been fulfilled. If the research is conducted or funded by the US Department of Defense (USDOD), the research may proceed only after the institution has certified to Director, Defense Research and Engineering that the duties of the Board under this section have been fulfilled.

ii If the research is DHHS-regulated, the research may proceed only after OHRP has reviewed and approved the research. If the research is conducted or funded by the US Department of Defense (USDOD), the research may proceed only after the Director, Defense Research and Engineering has reviewed and approved the research.

iii If the research is DHHS-regulated, the research may proceed only after OHRP has reviewed and approved the research. If the research is conducted or funded by the US Department of Defense (USDOD), the research may proceed only after the Director, Defense Research and Engineering has reviewed and approved the research.

iv For review using the expedited procedure, the prisoner representative may be the Designated Reviewer or may serve as a consultant to the Designated Reviewer.

Additional Comments regarding this review:

Who was the Prisoner Consultant on this review? _____

Did this consultant feel the research could be approved for the prisoner population?

Approval Box

At this time I recommend the research be: (Please check one, and sign/date)

- APPROVED.
Approved with Conditions, Minor Clarifications and/or Modifications back to the IRB Office. Note conditions below
Approved with Conditions, Major Clarifications and/or Modifications back to the Full IRB Meeting. Note conditions below
Do Not Recommend approval at this time. List Reasons. (Convened board must agree by a vote if study is not approved.)

Comments Section:

(Name) (Signature) (Date)