



CHECKLIST: Research Involving Prisoners		
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The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following the WORKSHEET: Criteria for Approval and Additional Considerations (HRP-314) when research involves Prisoners as subjects. This checklist must be used for all reviews (initial, continuing, modification, review by the convened IRB, and review using the expedited procedure.)

- For initial review using the expedited procedure and modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, the Designated Reviewer completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations. The Designated Reviewer attaches this checklist to CHECKLIST: Non-Committee Review (HRP-402). The Office of Human Research retains this checklist in the protocol file.
- For initial review using the convened IRB and for modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, one of the following two options may be used:
 1. The convened primary IRB reviewer completes the corresponding section of the TEMPLATE MINUTES (HRP-501) to document determinations required by the regulations along with protocol specific findings justifying those determinations, in which case this checklist does not need to be completed or retained.
 2. The convened primary IRB reviewer completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations and the Office of Human Research retains this checklist in the protocol file.

The research must meet one of the following two sets of criteria

1 Non-DHHS-Regulated Research Where a Subject Becomes Incarcerated (Check if "Yes". All must be checked)

- The research is NOT conducted or funded by DHHS.
- The subject was not incarcerated at the time of enrollment and subsequent incarceration was unexpected.
- The incarceration does not put the rights and wellbeing of the subject in jeopardy.
- The prisoner representative has been consulted.
- The terms of the subject's confinement does not inhibit the ethical conduct of the research.
- There are no other significant issues preventing the research from continuing as approved.
- This approval is limited to the individual subject and does not allow recruitment of prisoners.
- One of the following is true: (Check all that are true)
 - The subject will be at increased risk of harm if withdrawn from the research
 - The research presents no more than Minimal Riskⁱ and no more than inconvenience to the subjects.

2 Research Involving Prisonersⁱⁱ as Subjectsⁱⁱⁱ 45 CFR §46.305 (Check if "Yes". All must be checked)

- The research under review represents one of the following categories of research: (At least one must be checked.)
 - Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than Minimal Riskⁱ and no more than inconvenience to the subjects.
 - Study of prisons as institutional structures or of Prisoners as incarcerated persons, provided that the study presents no more than Minimal Riskⁱ and no more than inconvenience to the subjects.
 - 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).^{iv}
 - 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)
 - All groups may benefit from the research.
 - Prisoners are assigned to control groups which may not benefit from the research.^v
 - Epidemiologic studies in which the sole purpose is to describe the prevalence or incidence of a disease by identifying all cases or to study potential risk factor associations for a disease, the research presents no more than Minimal Riskⁱ and no more than inconvenience to the subjects, and Prisoners are not a particular focus of the research.

Provide protocol specific findings justifying this determination:
- 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.

Provide protocol specific findings justifying this determination:
- The risks involved in the research are commensurate with risks that would be accepted by non-Prisoner volunteers.

Provide protocol specific findings justifying this determination:
- 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.

Provide protocol specific findings justifying this determination:



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<input type="checkbox"/>	The information is presented in language which is understandable to the subject population. <i>Provide protocol specific findings justifying this determination:</i>
<input type="checkbox"/>	Adequate assurance exists that parole boards will not take into account a <u>Prisoner's</u> participation in the research in making decisions regarding parole, and each <u>Prisoner</u> is clearly informed in advance that participation in the research will have no effect on his or her parole. <i>Provide protocol specific findings justifying this determination:</i>
<input type="checkbox"/>	If the IRB finds 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 <u>Prisoners'</u> sentences, and for informing subjects of this fact. <i>Provide protocol specific findings justifying this determination:</i>

3 For Review by a Convened IRB (Check if "Yes". All must be checked)

<input type="checkbox"/>	A prisoner representative reviewed the research focusing on the requirements of this checklist.
<input type="checkbox"/>	The prisoner representative received all materials pertaining to the research.
<input type="checkbox"/>	The prisoner representative presented a review either orally or in writing at the convened meeting of the IRB or to the Designated Reviewer conducting

4 For Review Using the Expedited Procedure (Check if "Yes". All must be checked)

<input type="checkbox"/>	A prisoner representative reviewed the research focusing on the requirements of this checklist. ^{vi}
<input type="checkbox"/>	The prisoner representative received all materials pertaining to the research.
<input type="checkbox"/>	The prisoner representative concurs that the research involves no more than <u>Minimal Risk</u> ⁱ to the prisoner subjects

- ⁱ "Minimal risk" for research involving prisoners 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.
- ⁱⁱ "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.
- ⁱⁱⁱ 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 Department of Defense (DOD), 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.
- ^{iv} 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 Department of Defense (DOD), the research may proceed only after the Director, Defense Research and Engineering has reviewed and approved the research.
- ^v 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 Department of Defense (DOD), the research may proceed only after the Director, Defense Research and Engineering has reviewed and approved the research.
- ^{vi} The prisoner representative may be the Designated Reviewer or may serve as a consultant to the Designated Reviewer.