



CHECKLIST: Research Involving Prisoners

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The purpose of this checklist is to provide support for IRB members or the Designated Reviewer when reviewing research involving prisoners as subjects. This checklist must be used.

- For review using the expedited procedure this checklist is to be completed by the Designated Reviewer to document determinations required by the regulations and protocol specific findings justifying those determinations.
- For review using the convened IRB this checklist is to be completed by the convened IRB to document determinations required by the regulations and protocol specific findings justifying those determinations and retained 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 Incarceratedⁱ (All items must be “Yes”)

Yes	No	The research is not conducted, funded, or otherwise subject to DHHS, Veterans Administration (VA), or Department of Defense (DOD) regulations. ⁱⁱ
Yes	No	The subject was not incarcerated at the time of enrollment and subsequent incarceration was unexpected.
Yes	No	One of the following is true: (Check all boxes 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 The subject will be at increased risk of harm if withdrawn from the research 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 ⁱⁱⁱ and no more than inconvenience to the prisoner-subjects.

2 Research Involving Prisoners as Subjects (45 CFR §46 Subpart C) (All items in the left most columns must be “Yes” – Records or minutes must document protocol-specific findings justifying each of the following determinations.)

Yes	No	<p>The research under review represents one of the following categories of research: (Check all boxes that are true)</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 inconvenience to the subjects. <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. <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). ^{iv} <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: (Check box that is true) <input type="checkbox"/> All groups may benefit from the research. <input type="checkbox"/> Prisoners are assigned to control groups which may not benefit from the research. ^v <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 potential risk factor associations for a disease, the research presents no more than minimal risk and no more than inconvenience to the prisoner-subjects, and prisoners are not a particular focus of the research. <p><i>Provide protocol specific findings justifying this determination:</i></p>
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Yes	No	<p>Any possible advantages accruing to the prisoner through their 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 their ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired.</p> <p><i>Provide protocol specific findings justifying this determination:</i></p>
Yes	No	<p>The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers.</p> <p><i>Provide protocol specific findings justifying this determination:</i></p>
Yes	No	<p>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.</p> <p><i>Provide protocol specific findings justifying this determination:</i></p>
Yes	No	<p>The information is presented in language which is understandable to the subject population.</p> <p><i>Provide protocol specific findings justifying this determination:</i></p>
Yes	No	<p>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 is clearly informed in advance that participation in the research will have no effect on his or her parole.</p> <p><i>Provide protocol specific findings justifying this determination:</i></p>
Yes	No	<p>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 prisoners' sentences, and for informing subjects of this fact.</p> <p><i>Provide protocol specific findings justifying this determination:</i></p>



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- 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 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.
- ⁱⁱ If the research is subject to a federalwide assurance, it is subject to DHHS regulations regardless of whether the research is conducted or funded by DHHS.
- ⁱⁱⁱ “*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.
- ^{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.