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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 (HRP-314) when research involves Prisoners as subjects in a non-exempt study. Prisoner studies cannot be exempt except for research aimed at involving a broader subject population that only incidentally includes prisoners. Initial review requires the use of this checklist. Continuing review and modifications where the determinations relevant to this checklist have changed require an updated checklist.   * For review by the expedited procedure, the completed checklist is provided to the Designated Reviewer as an attachment in the assign review function. The Designated Reviewer may accept or require changes to this checklist via the “Submit Non-Committee Review” activity, either by uploading a revised checklist or including the changes that are requested in the review comment. The IRB Office retains this checklist in the protocol file. * For review by the convened IRB, the board completes this checklist and the IRB Office uploads this checklist in the “Submit Committee Review” activity and retains this checklist in the protocol file. | |
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| The research must meet ONE of the following three sets of criteria: | |
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| 1. [Waiver](https://www.govinfo.gov/content/pkg/FR-2003-06-20/html/03-15580.htm) **of the Applicability of Certain Provisions for Epidemiology Studies** | |
|  | 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****:*Click or tap here to enter text. |
| 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 or Veterans Administration (VA). |
|  | 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 Risk[[1]](#endnote-1) and no more than inconvenience to the subjects.  ***Provide protocol specific findings justifying this determination****:*Click or tap here to enter text. |
|  | |
| 1. **Research Involving Prisoners**[[2]](#endnote-2) **as Subjects**[[3]](#endnote-3)(Select a category, then ensure that all the other criteria in the remainder of the checklist are also met.) | |
|  | The research under review represents one of the [following categories of research](https://www.govinfo.gov/content/pkg/CFR-2016-title45-vol1/pdf/CFR-2016-title45-vol1-part46.pdf): (At least one must be checked.)  § 46.306 (a) (2) (i)- 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.  § 46.306 (a) (2) (ii)- 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.  § 46.306 (a) (2) (iii)- 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).[[4]](#endnote-4)  § 46.306 (a) (2) (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.[[5]](#endnote-5)  ***Provide protocol specific findings justifying this determination****:*Click or tap here to enter text. |
|  | 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****:*Click or tap here to enter text. |
|  | 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****:*Click or tap here to enter text. |
|  | 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****:*Click or tap here to enter text. |
|  | The information is presented in language which is understandable to the subject population.  ***Provide protocol specific findings justifying this determination****:*Click or tap here to enter text. |
|  | 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.  ***Provide protocol specific findings justifying this determination****:*Click or tap here to enter text. |
|  | 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.  ***Provide protocol specific findings justifying this determination****:*Click or tap here to enter text. |
|  | For IRB Staff Only |
|  | A prisoner representative reviewed the research focusing on the requirements of this checklist.[[6]](#endnote-6) |
|  | The prisoner representative received all materials pertaining to the research. |
|  | For convened IRB review, the prisoner representative presented either orally or in writing at the meeting or for review using the expedited procedure the prisoner representative concurred that the research involves no more than Minimal Riski to the prisoner subjects |

1. “*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. [↑](#endnote-ref-1)
2. “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. [↑](#endnote-ref-2)
3. 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. [↑](#endnote-ref-3)
4. 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. [↑](#endnote-ref-4)
5. 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. [↑](#endnote-ref-5)
6. For review using the expedited procedure, the prisoner representative may be the Designated Reviewer or may serve as a consultant to the Designated Reviewer. [↑](#endnote-ref-6)