



WORKSHEET: Prisoners		
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The purpose of this worksheet is to provide support for IRB members or the Designated Reviewer following 4.202 (**HRP-314**) - **WORKSHEET: Criteria for Approval** when research involves Prisoners as subjects. This worksheet may be used for all reviews (initial, continuing, modification, review by the convened IRB, and review using the expedited procedure) when research involves prisoners or prison employees as subjects.

- For initial review using the expedited procedure and modifications and continuing reviews where the determinations relevant to this worksheet made on the previous review have changed, the Designated Reviewer may utilize this worksheet to make determinations required by the regulations along with protocol-specific findings justifying those determinations. The Designated Reviewer documents their review in the electronic "Submit Designated Review" activity in eIRB+.
- If reviewing prison research by the expedited procedure, the following two options may be used:
 - For research **involving interaction with prisoners** or research **involving secondary research targeting prisoner records** reviewed by the expedited procedures:
 - Research involving interaction with prisoners or secondary research targeting prisoner records may be reviewed by expedited procedure, if a determination is made that the research involves no greater than minimal risk for the prison population being studied.
 - The prisoner representative must concur with the determination that the research involves no greater than minimal risk.
 - The prisoner representative must review the research as a reviewer. This may be as the sole reviewer or in addition to another reviewer, as appropriate.
 - Review of modifications and continuing review must use the same procedures for initial review using this expedited procedure including the responsibility of the prisoner representative.
 - Research with prisoners must comply with State law, as applicable.
 - For research involving **secondary research that does not target prisoner records, but only incidentally may include a prisoner's records** reviewed by the expedited procedure:
 - Research that does not target prisoner records but only incidentally may include a prisoner's records may be reviewed by the expedited procedure, if a determination is made that the research involves no greater than minimal risk of harm for the prison population being studied.
 - Review by a prisoner representative is not required.
 - The prisoner representative may review the research as a reviewer or consultant if designated by the IRB chair.
 - Review of modifications and continuing review must use the same procedures as initial review.
- For initial review using the convened IRB and for modifications and continuing reviews where the determinations relevant to this worksheet made on the previous review have changed, the convened IRB completes the corresponding section of the meeting minutes to document determinations required by the regulations along with protocol-specific findings justifying those determinations, in which case this worksheet does not need to be completed or retained.

NOTE: If a subject is incarcerated while enrolled in a study (1) check with applicable State law. If DoD requirements apply, see also 4.203 (HRP-318) - WORKSHEET: Additional Federal Agency Criteria.

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)

<input type="checkbox"/>	The research is NOT conducted or funded by DHHS or Veterans Administration (VA).
<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 does 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 <u>Minimal Risk</u> and no more than inconvenience to the subjects.
<input type="checkbox"/>	The institution has been notified of the proposed research to verify that the protocol plan complies with applicable State laws.



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2 Research Involving Prisonersⁱⁱ as Subjectsⁱⁱⁱ (Check if “Yes”. All must be checked)	
<input type="checkbox"/>	The research under review represents one of the following categories of research: (At least one must be checked.)
<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 <u>Minimal Risk</u> ⁱ and no more than inconvenience to the subjects.
<input type="checkbox"/>	Study of prisons as institutional structures or of <u>Prisoners</u> as incarcerated persons, provided that the study presents no more than <u>Minimal Risk</u> ⁱ and no more than inconvenience to the subjects.
<input type="checkbox"/>	Research on conditions particularly affecting <u>Prisoners</u> 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: (One box must be checked)
<input type="checkbox"/>	All groups may benefit from the research.
<input type="checkbox"/>	<u>Prisoners</u> 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 <u>Minimal Risk</u> ⁱ and no more than inconvenience to the subjects, and <u>Prisoners</u> are not a particular focus of the research. <i>Provide protocol-specific findings justifying this determination:</i>
<input type="checkbox"/>	Any possible advantages accruing to the <u>Prisoner</u> 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. <i>Provide protocol-specific findings justifying this determination:</i>
<input type="checkbox"/>	The risks involved in the research are commensurate with risks that would be accepted by non- <u>Prisoner</u> volunteers. <i>Provide protocol-specific findings justifying this determination:</i>
<input type="checkbox"/>	Procedures for the selection of subjects within the prison are fair to all <u>Prisoners</u> and immune from arbitrary intervention by prison authorities or <u>Prisoners</u> . 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 <u>Prisoners</u> who meet the characteristics needed for that particular research project. <i>Provide protocol-specific findings justifying this determination:</i>
<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</u> 's 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>
<input type="checkbox"/>	A Prisoner Representative reviewed the research focusing on the requirements of this worksheet. ^{vi}
<input type="checkbox"/>	The Prisoner Representative received all materials pertaining to the research.
<input type="checkbox"/>	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 <u>Minimal Risk</u> ⁱ to the Prisoner subjects
<input type="checkbox"/>	The institution has been notified of the proposed research to verify that the protocol plan complies with applicable State laws.

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.



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