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| The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following HRP-314 - WORKSHEET - Criteria for Approval 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). [[1]](#footnote-2)  When research involves Prisoners[[2]](#footnote-3) as subjects and falls into one of the following categories:   * The research involves greater than minimal risk; * The research is funded by a federal agency that has adopted Subpart D of the Common Rule; or * For Department of Defense (DOD) supported research, research involving prisoners of war or detainees[[3]](#footnote-4) as subjects.   If research involves greater than minimal risk and not DOD supported, the convened IRB and Designated Reviewers must use this checklist, or equivalent, for review of initial submissions, modifications, and continuing review.   * For initial review using the expedited procedure and modifications and continuing reviews that qualify for expedited review and where the determinations relevant to this checklist made on the previous review have changed, the Designated Reviewer completes this checklist or equivalent to document determinations required by the regulations along with protocol specific findings justifying those determinations. The Designated Reviewer to document determinations required by the regulations along with protocol specific findings justifying those determinations. The Designated Reviewer attaches this checklist to “Submit Non-Committee Review” activity. The HRSO retains this checklist in the protocol file. The Designated Reviewer must consult the HSRO’s Prisoner Representative when reviewing federally funded research that involves prisoners. * For initial review using the convened IRB and for modifications and continuing reviews where the determinations relevant to this checklist or equivalent made on the previous review have changed, one of the following two options may be used:  1. 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 checklist does not need to be completed or retained. 2. The convened IRB completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations and the HSRO staff uploads this checklist in the “Submit Committee Review” activity and retains this checklist in the protocol file.. | | |
| **IRB Number:** | |  |
| **Investigator:** | |  |
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| **The following criteria must be met if to qualify for review by the expedited procedure:** | | |
| The research is DOD supported (If not checked, review must be by a convened committee) | | |
| For research involving interactions with prisoners as subjects:  The prisoner representative reviews the submission as a reviewer or as a consultant; and  Review of modifications and continuing review use the same procedures for initial review using this expedited procedure, including the responsibility of the prisoner representative; and one of the following must be checked:  The research involves only minimal risk[[4]](#footnote-5) for the prison population being included and a prisoner representative concurs with this determination; or  The submission is for continuing review of research approved to involve prisoners where no participants have been enrolled and no additional risks have been identified - Expedited Category 8b.  For research that does not involve interaction with prisoners as subjects:  The research involves only minimal risk for the prison population being included[[5]](#footnote-6);  Review of modifications and continuing review use the same procedures as initial review3. | | |
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| Section 1: Non DOD or DHS Regulated Research with Subject Incarcerated after Enrollment | | |
| Non-DHHS-Regulated Research Where a Subject Becomes Incarcerated. *This review may be conducted by a designated reviewer*  (If applicable, all must be checked) N/A | | |
|  | The research is **NOT** conducted or supported 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 principal investigator asserted that it is in the best interest of the prisoner to continue to participate in the research while a prisoner. | |
|  | 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. | |
| Section 2. DOD and DHS Supported Research with Subject Incarcerated after Enrollment; May undergo preliminary review by Chair. If the study involves greater than minimal risk, the study must undergo review by the convened IRB at the next available meeting.  (If this section is applicable, all must be checked) | | |
| **2(a)**  **Preliminary Review by IRB Chair**: **(all of the following must be checked)**  **Note: *Must also meet criteria in Section 2(b)*** N/A | | |
| 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 principal investigator asserted that it is in the best interest of the prisoner to continue to participate in the research while a prisoner. | | |
| The subject will be at increased risk of harm if withdrawn from the research. | | |
| The IRB Chair determined that the prisoner-subject may continue to participate until the convened IRB approved the continuation of the prisoner in the research and this submission is on the agenda for the next applicable convened IRB meeting.[[6]](#footnote-7) | | |
| **2(b) Review by the convened IRB: (all of the following must be checked)** | | |
| 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 is present for the IRB this review. | | |
| The prisoner subject has capacity to consent to continue in the research. | | |
| The terms of the prisoner-subject’s confinement does not inhibit the ethical conduct of the research | | |
| The subject will be at increased risk of harm if withdrawn from the research. | | |
| There are no other significant issues preventing the research involving human subjects from continuing as approved[[7]](#footnote-8) [[8]](#footnote-9) | | |
| **Section 3. Research Enrolling Prisoners as Subjects**  (Check if “Yes” or “N/A”. All must be checked)[[9]](#footnote-10) | | |
|  | 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 Riskand 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 Risk 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).[[10]](#footnote-11) [[11]](#footnote-12)  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 and the research does not involve random assignment to a control group[[12]](#footnote-13).  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 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:* | |
|  | The information is presented in language which is understandable to the subject population.  *Provide protocol specific findings justifying this determination:* | |
|  | 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:* | |
|  | 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:* | |
|  | A prisoner representative reviewed the research focusing on the requirements of this checklist. | |
|  | The prisoner representative received all materials pertaining to the research. | |
|  | The prisoner representative presented a review either orally or in writing at the convened meeting of the IRB or, for expedited review, the prisoner representative concurred that the research involved no more than Minimal Risk to the prisoner subjects. | |
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1. This document satisfies AAHRPP elements I-9, II.4.A, II.4.B, II.5.A, II.5.B [↑](#footnote-ref-2)
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. [↑](#footnote-ref-3)
3. This includes any person captured, detained, held, or otherwise under the control of DOD personnel (military, civilian, or contractor employee). Such persons include: Enemy Combatant, Lawful Enemy Combatant, Unlawful Enemy Combatant, Enemy Prisoner of War, Retained Person, and Civilian Internee. Such persons do not include personnel of the DOD being held for law enforcement purposes. It does not include persons being held primarily for law enforcement purposes, except where the United States is the occupying power. This prohibition does not apply to activities covered by investigational new drug or investigational device provisions when the purpose is for diagnosis or treatment of a medical condition in a patient. Such treatment (e.g., an investigational new drug) may be offered to detainees or prisoners of war with their informed consent when the medical products are subject to FDA regulations investigational new drugs or investigational medical devices, and only when the same product may be available to DOD-affiliated personnel consistent with established medical practice. [↑](#footnote-ref-4)
4. Minimal risk for prisoners is defined by the regulations as 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 health persons (45 CFR.303(d)). [↑](#footnote-ref-5)
5. Review of a prisoner representative is not required for minimal risk research that does not involve interaction or intervention with prisoner subjects. [↑](#footnote-ref-6)
6. If the IRB Chair does not determine that the prisoner can continue in the research, the Chair must require that all research interactions, and interventions with the prisoner (including obtaining private identifiable information) cease until the convened IRB can review the request to continue the prisoner in the research. [↑](#footnote-ref-7)
7. This approval is limited to the individual prisoner-subject and does not allow recruitment of prisoners as subjects [↑](#footnote-ref-8)
8. The DoD Component Office must review the IRB’s approval to allow the prisoner to continue in the research. [↑](#footnote-ref-9)
9. For DoD and DHS funded research, the criteria must be met. For all other research, the IRB must consider each criterion and may approve the involvement of prisoners in the study if the research offers a potential for benefit not otherwise available to the prisoner. [↑](#footnote-ref-10)
10. 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. [↑](#footnote-ref-11)
11. If the research is conducted or funded by the Department of Defense (DOD) or its components, 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 [↑](#footnote-ref-12)
12. Note: OHRP Guidance states that studies involving random assignment do not meet this criterion even if with an active comparator. [↑](#footnote-ref-13)