|  |
| --- |
| 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 or equivalent must be used for all reviews (initial, continuing, modification, review by the convened IRB, and review using the expedited procedure.)[[1]](#footnote-2)* 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 or equivalent to document determinations required by the regulations along with protocol specific findings justifying those determinations. The Designated Reviewer attaches this checklist or equivalent to CHECKLIST: Non-Committee Review (HRP-402) or equivalent. The IRB Administration retains this checklist or equivalent in the protocol file.
* 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 TEMPLATE MINUTES (HRP-501) to document determinations required by the regulations along with protocol specific findings justifying those determinations, in which case this checklist or equivalent does not need to be completed or retained.
2. The convened IRB completes this checklist or equivalent to document determinations required by the regulations along with protocol specific findings justifying those determinations and the IRB Administration retains this checklist or equivalent in the protocol file.
 |
| **IRB Number:** |       |
| **Investigator:** |       |
|  |
| **The following criteria must be met to qualify for review by the expedited procedure:**  |
| [ ]  The research is not funded by the DOD – 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 as 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[[2]](#footnote-3) 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;  [ ]  Review of modifications and continuing review use the same procedures as initial review.  |
| The research must meet the criteria in Section 1 or Section 2. The research must meet criteria in Section 3, if applicable. |
|  |
| 1. Non-DHHS-Regulated Research Where a Subject Becomes Incarcerated. (If applicable, all must be checked) 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 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 and no more than inconvenience to the subjects. |
| **DOD Regulated Research where a Subject Becomes Incarcerated. N/A** [ ]  |
| [ ]  **Preliminary Review by IRB Chair**: **(If this item is checked, the next five rows 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 principal investigator asserted that it is in the best interest of the prisoner to continue to participate in the research while a prisoner.  |
| [ ]  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.[[3]](#footnote-4) [[4]](#footnote-5) |
| [ ]   **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 |
| [ ]  There are no other significant issues preventing the research involving human subjects from continuing as approved[[5]](#footnote-6) [[6]](#footnote-7) |
| The incarceration does not put the rights and wellbeing of the subject in jeopardy. |
| **2. Research Involving Prisoners**[[7]](#footnote-8) **as Subjects**  (Check if “Yes” or “N/A”. 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 Risk[[8]](#footnote-9) 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 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).[[9]](#footnote-10) [[10]](#footnote-11)[ ]  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.[[11]](#footnote-12) [[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. |
|  |
| 1. For Research Involving Prisoners of the State of California or of County or Local Jails in California[[13]](#footnote-14) (Check if “Yes” or “N/A”. All must be checked)
 |
| [ ]  | The research involves one of the following categories:[ ]  A drug or treatment available only through a treatment protocol or treatment IND, where the subject’s physician has determined that access to that drug is in the best medical interest of the prisoner subject.[ ]  Behavioral research of the possible causes, effects and processes of incarceration and studies of prisons as institutional structures or of prisoners as incarcerated persons which present minimal or no risk and no more than mere inconvenience to the prisoner subjects.  |
| [ ]  | Behavioral modification techniques used in the research techniques are medically and socially acceptable means by which to modify behavior and do not inflict permanent physical or psychological injury. (“N/A” if no behavioral modification techniques are used in the research) |
| [ ]  | The California Department of Corrections and Rehabilitation (CDCR) has approved the research, if the research involves state (as opposed to county or local) prisoners.[[14]](#footnote-15) *Note that state prisoners are sometimes detained in county or local jails.* **(“N/A” if no State of California** **prisoners)** |
| [ ]  | Any waiver of informed consent is approved by (CDCR)[[15]](#footnote-16) **(“N/A” if no waiver or no State of California** **prisoners)**  |

1. 1 Research involving any person captured, detained, held, or otherwise under the control of DoD personnel (military and civilian, or contractor employee) is prohibited. [↑](#footnote-ref-2)
2. 2 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-3)
3. 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 require to continue the prisoner in the research. [↑](#footnote-ref-4)
4. 3 The research involving human subjects does not have to meet one of the six allowable categories of research as described in Section 3 above. [↑](#footnote-ref-5)
5. This approval is limited to the individual prisoner-subject and does not allow recruitment of prisoners as subjects [↑](#footnote-ref-6)
6. The DoD Component Office must review the IRB’s approval to allow the prisoner to continue in the research. [↑](#footnote-ref-7)
7. “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-8)
8. “*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. [↑](#footnote-ref-9)
9. 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-10)
10. 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 [↑](#footnote-ref-11)
11. 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-12)
12. 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 [↑](#footnote-ref-13)
13. This requirement does not apply to prisoners in federal prisons. [↑](#footnote-ref-14)
14. See Cal Penal Code §§ 3500-3524; 15 Cal. Code Reg. 3369.5. Information on CDCR approval processes can be found in the agency’s Operations Manual (Article 19), online at <https://www.cdcr.ca.gov/regulations/wp-content/uploads/sites/171/2023/05/2023-DOM.pdf>; and on the agency’s website at <https://www.cdcr.ca.gov/research/research-requests/>. [↑](#footnote-ref-15)
15. The California Department of Corrections and Rehabilitation will limit this approval to behavioral research where requiring informed consent is unnecessary or would significantly inhibit the conduct of the research. [↑](#footnote-ref-16)