The purpose of this checklist is to provide support for IRB members or the designated reviewer following the *OIA-314 WORKSHEET: Criteria for Approval and Additional Considerations*, or equivalent, when research involves prisoners[1,2] as subjects. This checklist, or equivalent, may be used for all reviews (initial, continuing, amendment, review by the convened IRB, and review using the expedited procedure. It does not need to be completed or retained.

IRB Number:	
Investigator:	

The following criteria must be met to qualify for review by the expedited procedure. If all items below cannot be checked, review must be conducted by the convened IRB: (Check if "yes." All must be checked to qualify for expedited review.)

- ☐ The research is not funded by the Department of Defense (DOD) – If not checked, review must be conducted by convened IRB.
- ☐ The research involves one of the following:
  - ☐ 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[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.[4]
  - ☐ No interactions with prisoners as subjects:
    - ☐ The research involves only minimal risk for the prison population being included,[5] and
    - ☐ Review of modifications and continuing review use the same procedures as initial review.[6]

To be approvable, the research must meet the criteria in Section 1 or Section 2. Additionally, the research must meet criteria in Section 3, if applicable.

Section 1: Research in Which a Subject Becomes Incarcerated (Choose from one of the two options below)

- ☐ **Non-Department of Health and Human Services (DHHS)-Regulated Research in Which 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 in which a Subject Becomes Incarcerated.**[7] (If applicable, then "review by the convened IRB" must be checked. "Preliminary review by IRB chair" should be checked when the situation cannot wait for review by the convened IRB) N/A ☐
  - ☐ **Preliminary Review by IRB Chair**: **(If this item is checked, the next five rows must be checked, i.e., the preliminary review by IRB chair may be completed pending convened IRB review.)**
    - ☐ 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.

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[1] "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.

[2] Research involving any person captured, detained, held, or otherwise under the control of DOD personnel (military and civilian, or contractor employee) is prohibited.

[3] 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 healthy persons - 45 CFR 46.303(d).

[4] OHRP Guidance Expedited Review: Categories of Research that may be Reviewed Through an Expedited Review Procedure (1998)

[5] Review of a prisoner representative is not required for minimal risk research that does not involve interaction or intervention with prisoner-subjects.

[6] The research involving human subjects does not have to meet one of the allowable categories of research as described in Section 2 below.

[7] DOD Instruction 3216.02 Section 3.9(c)

		☐	The IRB chair determined that the prisoner-subject may continue to participate until the convened IRB approves the continuation of the prisoner in the research and this submission is on the agenda for the next applicable convened IRB meeting.[8]
	☐	**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 this review by the IRB.
		☐	The prisoner-subject has capacity to consent to continue in the research.
		☐	The terms of the prisoner-subject's confinement do not inhibit the ethical conduct of the research.
		☐	There are no other significant issues preventing the research involving human subjects from continuing as approved[9, 10]

Section 2: Research Involving Prisoners[11] 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 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).[12,13] ☐ 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.[14, 15] ☐ 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 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. *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:*

[8] 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 identifiable private information) cease until the convened IRB can review the requirement to continue the prisoner in the research.
[9] This approval is limited to the individual prisoner-subject and does not allow recruitment of prisoners as subjects.
[10] The DOD Component Office must review the IRB's approval to allow the prisoner to continue in the research.
[11] "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.
[12] If the research is DHHS-regulated, the research may proceed only after the institution has certified to Office for Human Research Protections (OHRP) that the duties of the Board under this section have been fulfilled.
[13] If the research is conducted or funded by the 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
[14] 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.
[15] If the research is conducted or funded by the 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

☐	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 their 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, or equivalent. ☐ N/A. A prisoner representative is not required because the study involves no intervention or interaction with prisoners.
☐	The prisoner representative received all materials pertaining to the research. ☐ N/A. A prisoner representative is not required because the study involves no intervention or interaction with prisoners.
☐	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. ☐ N/A. A prisoner representative is not required because the study involves no intervention or interaction with prisoners.
Section 3: For Research Involving Prisoners of the State of California or of County or Local Jails in California[16] (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 Investigational New Drug (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 [risk] or no risk and no more than mere inconvenience to the prisoner-subjects. ☐ Records-based biomedical research using existing information, without prospective interaction with human subjects
☐	Behavioral modification techniques used in the research procedures 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.[17] *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)[18] **("N/A" if no waiver or no State of California prisoners)**

[16] This requirement does not apply to prisoners in federal prisons.
[17] See California Penal Code 3500-3524; 15 Cal. Code Reg. 3488. Information on CDCR approval processes can be found in the agency's Research Oversight Committee Guidelines at Guidelines for CDCR Research Application and available on their website at Research Requests - Office of Research (ca.gov)
[18] 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.