IRB Member Checklist for Projects involving Prisoners (subpart C)

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| **IRB Meeting Date:** Click or tap to enter a date. | **eBridge #:** Click or tap here to enter text. |
| **Principal Investigator:** Click or tap here to enter text. | **Reviewer Name:** Click or tap here to enter text. |

This checklist should be used with the *New Protocol Reviewer Checklist* for projects which request the inclusion of subjects who meet the definition of prisoners.

IRB Committee Members should apply the criteria outlined within the *IRB Member SOP: Research involving Prisoners.*

# **Permitted Research Involving Prisoners**

Except as provided in paragraph (a) of this 45 CFR 46.306, biomedical or behavioral research conducted or supported by DHHS shall not involve prisoners as subjects.

The IRB must look at each element separately, considering the study goals, aims and objectives. Please indicate which category the propose research meets:

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| *§46.306(a) The proposed research involves solely* ***one of the following categories****:* |
|[ ]  *(i) 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;**Rationale for choosing this category:* Click or tap here to enter text. |
|[ ]  *(ii) 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;**Rationale for choosing this category:* Click or tap here to enter text. |
| [ ]  | *(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) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of his intent to approve such research;* *Rationale for choosing this category:* Click or tap here to enter text.*•Note that selecting category (iii) triggers the requirement for Secretarial consultation. For more information, review IRB Member SOP: Research Involving Prisoners.*  |
| [ ]  | *(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. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of the intent to approve such research.**Rationale for choosing this category:* Click or tap here to enter text.*•Note that selecting category (iv) may trigger the requirement for Secretarial consultation. For more information, review IRB Member SOP: Research Involving Prisoners.* *•Please notify HRPP Director when selecting option (iv).* |

# **Per Federal Regulations 46.305(a):**

IRB shall review research covered by this subpart and approve such research only if it finds that all the sections have been met:

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| **Sections/Provision** |
|[ ]  (1) the research under review represents one of the categories of research permissible under [§46.306](http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm#46.306#46.306)(a)(2) – See above, [**Permitted Research Involving Prisoners**](#_Permitted_Research_Involving); |
|[ ]  (2) 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; |
|[ ]  (3) the risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers; |
|[ ]  (4) 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; |
|[ ]  (5) the information is presented in language which is understandable to the subject population |
|[ ]  (6) 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; and |
|[ ]  (7) where the Board finds there may be a need for follow-up examination or care of participants 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 participants of this fact |

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| **Reviewer Comments**  |
| Click or tap here to enter text. |

Reviewer Name:Click or tap here to enter text. Date:Click or tap to enter a date.