Reviewer guide [[Subpart C](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46#subpart-C)]: Prisoners as research participants

This reviewer guide should be completed and retained in the study file.

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| --- | --- |
| **PI Name:** | Click or tap here to enter text. |
| **Protocol Title:** | Click or tap here to enter text. |
| **IRB #:** | Click or tap here to enter text. |
| **IRB Reviewer(s):** | Click or tap here to enter text. |
| **Date Completed:** | Click or tap here to enter text. |

# Category of Research:

The research falls into one or more of these categories:

|  |  |
| --- | --- |
|  | The research proposes to study the possible causes, effects, and processes of incarceration, and of criminal behavior. The study presents no more than minimal risk and no more than inconvenience to the participants. |
|  | The research proposes to study prisons as institutional structures or to study prisoners as incarcerated persons. The study presents no more than minimal risk and no more than inconvenience to the subjects. |
|  | The research proposes to study the conditions particularly affecting prisoners as a class (e.g., research on hepatitis which is more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults).  *If the research is conducted or supported by DHHS, the Secretary has consulted with appropriate experts including experts in penology, medicine, and ethics and the Secretary has published notice, in the Federal Register, of his/her intent to approve such research. Research proposals in this category that are not conducted or supported by HHS do not require a Secretarial consultation.* |
|  | The research proposes to study the practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well­being of the participants.  *If the research is conducted or supported by DHHS and the research requires the assignment of prisoners to control groups that may not benefit from the research, the Secretary has consulted with appropriate experts including experts in penology, medicine, and ethics and the Secretary has published notice, in the Federal Register, of his intent to approve such research. Research proposals in this category that are not conducted or supported by HHS do not require a Secretarial consultation.* |

**COMMENTS:** Click or tap here to enter text.

# Additional Requirements:

In addition to determining the study falls under one of the categories detailed above, the IRB must determine the following requirements are met:

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|  | 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. |
|  | The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers. |
|  | Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. |
|  | The information is presented in language which is understandable to the subject population. |
|  | 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. |
|  | 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. |

**COMMENTS:** Click or tap here to enter text.