**Institutional Review Board**

**Prisoners as Subjects**

This worksheet is to help IRB members determine whether the additional protections pertaining to biomedical and behavioral research involving prisoners as subjects are met as per 45 CFR 46 Subpart C.[[1]](#footnote-1)

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| **Terms** | | |
| Prisoners | Any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under criminal or civil statue, individuals detained in other facilities by virtue of statues or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing. This definition includes: | |
|  | Individuals in hospitals or alcohol and drug treatment facilities, who are under court order |
|  | Individuals in work-release and house-arrest programs |
|  | Minors and adults |
|  | NOT individuals on parole |
| Non-Prisoner Minimal Risk | The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests | |
| Prisoner Minimal Risk | The probability and magnitude of physical or psychological that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons | |

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| Protocol ID |  |
| Title of Protocol |  |
| PI/Researcher(s) |  |

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| **General Considerations: (all must be checked)** | |
|  | The research is supported by the HHS |
|  | The research is material to the lives of the prisoners |
|  | The institution responsible for the conduct of the research has certified to the Secretary that the IRB has approved the research |
|  | A majority of the IRB has no association with the prison(s) involved, apart from their membership on the Board |
|  | At least one member of the Board shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one IRB only one IRB need satisfy this requirement[[2]](#footnote-2) |

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| **General Considerations for Research Design (all must be checked)** | |
|  | Consent is obtained freely without coercion and without undue influence |
|  | Incentives to take part in the research are appropriate to the research setting and subject population |
|  | Consent forms clarify the type of information available to correction staff, such as a final report containing aggregate data but not information that would identify individuals |
|  | PI/Researcher has specified the limits of confidentiality and what information can never be confidential within a prison, such as prisoners’ threats to hurt themselves or others or professed plans to escape |

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| **General Considerations for Assessing Risk (all must be checked)** | | |
|  | The PI/Researcher has worked in conjunction with prison staff to develop strategies for managing the risks presented when inmates are asked potentially emotionally charged questions | |
|  | Potential Breaches of Confidentiality are Minimized | |
|  |  | Nature of Conviction, i.e., information that may be publicly available in free society becomes private within the prison |
|  |  | Health Status, i.e., health information about a prisoner may be private and could stigmatize the prisoner if not kept confidential |
|  |  | Prison Life, e.g., inability to guarantee confidentiality within focus groups |

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| **Section A: Research with prisoners must fall under one of the following categories:[[3]](#footnote-3)** | |
|  | 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 (e.g., vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; 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 |
|  | 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 his intent to approve such research |

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| **Section B: Criteria for research that involves prisoners as research subjects (all must be checked)** | |
|  | The research falls under at least one of the categories laid out in Section A |
|  | 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, do not impair the prisoners’ ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison |
|  | 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. 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 |
|  | 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 |

1. Information in the worksheet comes from 45 CFR 46 Subpart C and the course “Research with Prisoners – SBE” through CITI. [↑](#footnote-ref-1)
2. The prisoner representative must be a voting member of the IRB. Suitable members that would meet the prisoner or prisoner representative requirement include: former prisoners, prison chaplains, prison psychologists, prison social workers, other prison service providers, prisoners’ rights advocates, etc. Institutions have the option of stipulating that the prisoner representative will only count toward a quorum when in attendance at a convened meeting and reviewing studies covered by Subpart C. [↑](#footnote-ref-2)
3. Examples of social and behavioral sciences research in these categories include: age at first arrest as a predictor of adult criminal history, effects of overcrowding on prison populations, the influence of prison-awarded incentives on retention in substance abuse treatment programs, the use of true crime/detective stories as bibliotherapy, social support systems in prisons, the functioning of pseudo-families in prison [↑](#footnote-ref-3)