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| Study ID |  | PI |  | Funding Source |  |

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| Why are all or some of the subjects considered prisoners? | | |
|  | | |
| Select and complete either A or B. To involve prisoners in research, either A or B must be met. | | |
| 1. The research under review represents one of the categories of research permissible below: | | |
|  | | 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) 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 *[Reporting to and approval by HHS may not be required for non-HHS funded studies]* |
|  | | 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 *[Reporting to and approval by HHS may not be required for non-HHS funded studies]* |
| *Why does the research represent the selected category?* | | |
| 1. The research’s sole purposes are epidemiological in nature: | | |
|  | | To describe the prevalence or incidence of a disease by identifying all cases. |
|  | | To study potential risk factor associations for a disease. |
| *Why does the research represent the selected category?* | | |
|  | The research presents no more than minimal risk and no more than inconvenience to the prisoner-subjects.  *Why does the research meet this criterion?* | |
|  | Prisoners are not a particular focus of the research.  *Why does the research meet this criterion?* | |
| To involve prisoners in research, the following criteria must be met: | | |
|  | 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.  *Why does the research meet this criterion?* | |
|  | The risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers.  *Why does the research meet this criterion?* | |
|  | 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.  *Why does the research meet this criterion?* | |
|  | The information is presented in language which is understandable to the subject population.  *Why does the research meet this criterion?* | |
|  | 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.  *Why does the research meet this criterion?* | |
|  | 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.  *Why does the research meet this criterion?* | |
| No Yes Is this research HHS funded? If yes, OHRP Certification is REQUIRED. Research involving prisoners may proceed **only after receipt of the OHRP authorization letter.** | | |

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| IRB determination made by: | | | | |
|  | | | | |
| Full board | Name of individual completing this form: |  | Meeting date |  |
|  | | | | |

**HHS Funded - Needs OHRP Certification (Complete Certification section).**

Sent to OHRP, Date

Approved by OHRP. Date

NOTE: Research involving prisoners may proceed **only after receipt of the OHRP authorization letter.**

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| HHS Certification Section – Required if HHS Funded | | | | |
| A. | No  Yes | Are multiple institutions engaged in the same research study involving prisoners?  If no, MSU must certify. Complete B.  If yes, complete 1 and 2. | | |
|  |  | 1 | No  Yes | Did or will MSU rely upon the review of an IRB operated by another institution engaged in the research?  If no, MSU must certify. Complete B.  If yes, which institution(s)? Note: A formal reliance agreement is needed. |
|  |  | 1 | No  Yes | Did or will that IRB or other institution certify to OHRP on behalf of both institutions?  If no, MSU must certify. Complete B.  If yes, confirmation in writing is needed. |
|  |  | If both answers to 1 are yes, certification by MSU is not needed. However, prisoners cannot be involved until OHRP authorization is received by the other institution. | | |
|  |  | 2 | No  Yes | Did or will another institution(s) engaged in the research rely upon the review of an MSU IRB?  If no, both MSU and the other institution must certify individually. Complete B. If yes, which institution(s)? Note: A formal reliance agreement is needed. |
|  |  | 2 | No  Yes | Did or will MSU certify to OHRP on behalf of both institutions?  If no, both MSU and the other institution(s) must certify individually. Complete B.  If yes, confirmation in writing is needed. |
|  |  | If both answers to 2 are yes, MSU may certify for the institution(s) and certification by the other institution(s) is not needed. However, prisoners cannot be involved until OHRP authorization is received. Complete B. | | |
| B. | The institution shall certify to the Secretary, in such form and manner as the Secretary may require, that the duties of the Board under this section have been fulfilled.  OHRP requires the responsible institution to submit a copy of the research proposal:  the IRB approved protocol;  any relevant HHS grant application or proposal;  any IRB application forms required by the IRB; and  any other information requested or required by the IRB to be considered during initial IRB review.  Certification should include:  OHRP Federalwide Assurance number  IRB registration number for the designated IRB  Date(s) of IRB meeting(s) in which the protocol was considered, including a brief chronology that encompasses the date of initial IRB review and the date of subpart C review, if not done at the time of initial review  The institution responsible for the conduct of the research has certified to the Secretary that the Institutional Review Board has approved the research under §46.305 of this subpart  Certification must indicated IRB reviewed research under Subpart C and made the seven findings as required by the regulations (45 CFR 46.305(a)) | | | |