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| **Instructions** | | |
| * Use this template when there will be the involvement of prisoners in a study. * CLICK™ IRB   + Include template with a New Study Submission.   + Upload completed template to the MSU Additional Study Information SmartForm page. * See HRPP Manual 6-8-B, Prisoners, for more information. | | |
| Complete questions 1 – 8. | | |
| 1 | Study title. | |
| 2 | Complete either 2A or 2B. | |
| 2A | The research under review represents one of the categories of research permissible under 45 CFR 46.306(a)(2) (select one): | |
|  | 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? | |
| 2B | The research’s sole purposes are to (select one): | |
|  | Describe the prevalence or incidence of a disease by identifying all cases. |
|  | Study potential risk factor associations for a disease. |
| Why does the research represent the selected category? | |
| Explain why the research presents no more than minimal risk and no more than inconvenience to the prisoner-subjects. | |
| Explain why prisoners are not a particular focus of the research. | |
| 3 | Explain why 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. | |
| 4 | Explain why the risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers. | |
| 5 | Explain why 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. | |
| 6 | Explain how the information will be presented in language which is understandable to the subject population. | |
| 7 | Explain how 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. | |
| 8 | Explain whether there may be a need for follow-up examination or care of participants after the end of their participation. If there is such a need, explain how 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. | |