**This form should be used when prisoners are a targeted study population.**

* **Prisoner:** Any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

**To be given the correct regulatory category, language must be documented, reviewed, and approved as part of the IRB materials. Provide protocol specific justification for each item to assist the IRB with their review.**

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| --- |
| **Basic Information** |
| **Title of Study:** |       |
| **Short Title:** |       |
| **Principal Investigator Name:** |       |
| **Section 1: General Information**  |
| What activities will prisoners perform or complete for the research study?       |
| Where will the prisoners be located?      |
| Has permission from the facility the prisoners are housed been obtained?[ ]  Yes [ ]  No [ ]  Pending:       |
| Specify the status of the prisoners:[ ]  Individuals involuntarily confined or detained in a penal institution. **Explain:**      [ ]  Individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution. **Explain:**      [ ]  Individuals detained pending arraignment, trial, or sentencing. **Explain:**      [ ]  Other individuals involuntarily detained under a criminal or civil statute. **Explain:**        |
| Will any of the prisoners also be minors? [ ]  Yes [ ]  No**If Yes, complete the *Appendix for Children/Wards*** |
| **Section 2: Prisoner Categories (45 CFR 46.306(a)(2))** **Select the most appropriate box below** |
| [ ]  | Category 1* The 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 participants
 |
| [ ]  | Category 2* Research involving the 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 participants
 |
| [ ]  | Category 3* Research involving research on conditions particularly affecting prisoners as a class (for example, research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults)
 |
| [ ]  | Category 4* Research involving research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the participant
 |
| **Please provide justification for the request to include prisoners:**       |
| **Section 3: Other Considerations (45 CFR 46.305)**  |
| Research where 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.**\*If Yes, explain:**      | [ ]  Yes\* [ ]  No |
| The risks involved are commensurate with risks that would be accepted by non-prisoner volunteers.**\*If No, explain:**      | [ ]  Yes [ ]  No\* |
| Procedures for the selection of participants within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners.**\*If No, explain:**      | [ ]  Yes [ ]  No\* |
| 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.**\*If No, explain:**      | [ ]  Yes [ ]  No\* |
| The information is in language which is understandable to the population.**\*If No, explain:**      | [ ]  Yes [ ]  No\* |
| There may be a need for follow-up examination or care of participants after the end of their participation. If so, adequate provisions have been made.**\*If No, explain:**      | [ ]  Yes [ ]  No\* |