

## CHECKLIST FOR PRINCIPAL INVESTIGATORS TO COMPLETE REGARDING RESEARCH INVOLVING PRISONERS

Definition of Prisoners, when enrolled in research:

- “Prisoner” means 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.
  - detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and
  - detained pending arraignment, trial or sentencing.
- Minimal risk is
  - the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives
  - or in the routine medical, dental or psychological examination of healthy persons.

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|---|-----|----|
| 1. Are prisoners the particular focus of the research?  | Yes | No |
| 2. Does the study involve:  |     |    |
| ○ Causes, effects, and process of incarceration and criminal behavior?  | Yes | No |
| ○ Prisoners as institutional structures?  | Yes | No |
| ○ Prisoners as incarcerated persons?  | Yes | No |
| ○ Conditions affecting prisoners as a class (examples- hepatitis research, alcoholism, drug addiction, sexual assaults)                         | Yes | No |
| 3. Will the selection of participants within the prison be immune from arbitrary intervention by prison authorities or other prisoners?         | Yes | No |
| 4. Will a control group of prisoners be selected randomly from a group of available who meet the characteristics needed for the research study? | Yes | No |
| 5. Does the research involve not more than minimal risk to prisoner participants?   | Yes | No |
| 6. Does the research involve not more than inconvenience to prisoner participants?  | Yes | No |
| 7. Would the risks from participation in the research be acceptable to non-prisoners?   | Yes | No |
| 8. Does the research require the assignment of prisoners to a control group?  | Yes | No |
| 9. Will there be a potential direct benefit to prisoner participants?   | Yes | No |

10. Will the research use practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the participant? Yes No
11. Will the research involve potential benefits to the prisoner (improved living conditions, quality of food, medical care, amenities and opportunities for earnings) that might affect the prisoner's ability to weigh the risks of the research against the values of the potential benefits in a prisoner setting? Yes No
12. Does the protocol include assurance that parole boards will not take into account a prisoner's participation in the research when making decisions regarding parole? Yes No
13. Does the consent document specifically state that parole boards will not take into account a prisoner's participation in the research when making decisions regarding parole? Yes No
14. Will prisoner participants have access to follow-up care at the end of their participation in the research? (When no follow-up care will be necessary, due to the type of research being conducted, mark N/A)  
Yes No N/A