

**Brown University**

**Appendix B. Prisoners as Subjects**

**Requires Full Board Review**

**Protocol Title:**

**Principal Investigator (PI):**

**IRB Protocol # (if amendment):**

**Date of submission:** Click here to enter a date.

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| **This Appendix must be completed by the PI and included when a proposed study includes prisoners as participants; or obtains, uses, studies, or analyzes prisoners’ identifiable private information/identifiable biospecimens.**Federal regulations and Brown University policy require research involving prisoners to be classified into one of four categories.  |
| 1. Please review the four categories of [research involving prisoners](#prisoner) that may be approved by the IRB and select which category best describes your protocol (you **must** be able to select a category for your research with prisoners to be approved): |
| [ ]  Category 1 | The research involves the study of the possible causes, effects, and processes of incarceration, and of criminal behavior. The study presents no more than minimal risk and no more than inconvenience to the subjects. |
| [ ]  Category 2 | The research involves study of prisons as institutional structures or of prisoners as incarcerated persons. The study presents no more than minimal risk and no more than inconvenience to the subjects. |
| [ ]  Category 3 | The research involves a study on conditions particularly affecting prisoners as a class. |
| [ ]  Category 4 | The research involves a study on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the participants. |
| 2. The following questions are those that the IRB must consider when determining whether your use of prisoners in the proposed research can be approved. Please answer all of the questions below. [You may need to return to your protocol application and/or consent documents to provide sufficient information in your application to justify your selections below.]  |
| [ ]  Yes [ ]  No[ ]  N/A | a. Are any possible advantages accruing to the prisoner through their participation, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, of such a magnitude that their ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired? |
| ☐ Yes ☐ No | b. Are the risks involved in the research commensurate with risks that would be accepted by non-prisoner volunteers? |
| ☐ Yes ☐ No | c. Are the procedures for the selection of participants within the prison fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners? |
| ☐ Yes ☐ No[ ]  N/A | d. Are control participants selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project? |
| ☐ Yes ☐ No[ ]  N/A | e. Is the information presented in language which is understandable to the subject population? |
| ☐ Yes ☐ No[ ]  N/A | f. Does adequate assurance exist that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole? |
| ☐ Yes ☐ No[ ]  N/A | g. Does adequate assurance exist that each prisoner is clearly informed in advance that participation in the research will have no effect on their parole? |
| ☐ Yes ☐ No[ ]  N/A | h. Has adequate provision been made for follow-up examination or care of participants after the end of their participation, taking into account the varying lengths of individual prisoners' sentences and informing participants of this fact? |

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 ([45 CFR 46.303(c)](https://www.ecfr.gov/on/2018-07-19/title-45/subtitle-A/subchapter-A/part-46#46.303)).

Individuals are prisoners if they are in any kind of penal institution, such as a prison, jail, or juvenile offender facility, and their ability to leave the institution is restricted. Prisoners may be convicted felons, or may be untried persons who are detained pending judicial action (e.g., arraignment or trial). ([Office for Human Research Protections, Prisoner Research FAQs](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/prisoner-research/index.html)).

Common examples of the application of the regulatory definition of prisoner are as follows:

Individuals who are detained in a residential facility for court-ordered substance abuse treatment as a form of sentencing or alternative to incarceration are prisoners; Individuals with psychiatric illnesses who have been committed involuntarily to an institution as an alternative to a criminal prosecution or incarceration are prisoners; Parolees who are detained in a treatment center as a condition of parole are prisoners.