Human Subjects Research Addendum for Research Involving Incarcerated Persons

Overview of Research with Incarcerated Persons

The regulations in [Subpart C](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-C) are applicable to **all** biomedical and behavioral research conducted or supported by the Department of Health and Human Services involving prisoners as subjects and **may** be applied to research involving justice involved persons who do not meet the federal definition of prisoner. State or local laws that limit or prohibit research with incarcerated persons beyond what is stated in Subpart C will be observed. Approval of research with incarcerated persons is still subject to State or local laws that may further limit or even prohibit the research described in the application materials. Prisoners may be under constraints due to their incarceration which could affect their ability to make a truly voluntary and uncoerced decision about whether or not to participate as subjects in research, it is the purpose of Subpart C to provide additional safeguards for the protection of prisoners involved in activities to which this subpart is applicable. [Prisoners](45%20CFR%2046.303(c)) are 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.

Section 1. Research Type

1. According to [45 CFR 46.306](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-C/section-46.306), research involving prisoner participants may be permitted if it falls under one of the following categories.

Select all that apply.

Study involves 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 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.

Is this research a study of 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?

2. Justification of category selection

Describe below how your project meets one of the four categories above.

Section 2. Details Regarding Research Involving Incarcerated Persons

1. Benefits of participation

Describe 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.

2. Risks of participation

Describe how the risks involved in the research are commensurate with the risks that would be accepted by non-prisoner volunteers.

3. Protection of data

Describe what procedures are in place to protect data during collection and storage.

4. Equitable selection of participants

Describe how the procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners.

5. Accessibility of participant information

Describe how the information will be presented in language which is understandable to the subject population.

6. Assurances of participant protections

Describe what adequate assurances exist that parole boards or other authorities will not take into account a prisoner's participation in the research in making decisions regarding parole or early release, and is each prisoner clearly informed in advance that participation in the research will have no effect on his or her parole or early release:

7. Provisions and resources for participants

If there may be a need for follow-up examination or care of participants after the end of their participation, describe what adequate provisions been made for such examination or care, considering the varying lengths of individual prisoners' sentences, and for informing participants of this fact: