

CUNY HRPP Policy: Prisoners as Research Subjects

1. Applicability

This policy applies to all human subject research involving prisoners in which CUNY becomes engaged.

2. Definitions

2.1. Minimal risk

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.

2.2. 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.

3. IRB Review

Research involving prisoners as research subjects must be reviewed and approved by an Institutional Review Board (IRB) prior to its initiation.

3.1. Research involving prisoners may be exempt from IRB review ONLY when the research is aimed at a broader subject population that only incidentally includes prisoners. See [CUNY HRPP Procedures: Human Subjects Research Exempt from IRB Review for exempt categories](#).

3.2. Research involving prisoners CANNOT be exempt from IRB review when prisoners are the target population.

3.3. Research involving prisoners may be reviewed on an expedited basis, ONLY when the Associate University Provost for Research Administration and Compliance or his/her designee concurs that the research meets the criteria for expedited review.

3.3.1. At least one of the reviewers conducting the review on an expedited basis must be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity.

3.4. In addition to meeting the requirements outlined in [CUNY HRPP Procedures: Convened IRB Review](#), when reviewing research involving prisoners, the convened IRB must meet the following requirements:

3.4.1. A majority of the Board (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the Board.

3.4.2. At least one member of the Board shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in the capacity.

4. **Criteria for Inclusion of Prisoners in Research**

CUNY UI-IRBs may approve research involving prisoners as subjects only when the research meets one of the following criteria:

- 4.1. 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.
- 4.2. 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.
- 4.3. 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 one of the following consultations have taken place:
 - a. For research that is conducted or supported by the US Department of Health and Human Services (HHS), the Secretary of HHS or his/her designee 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.
 - b. For research that is not conducted or supported by the HHS, the Vice Chancellor for Research has consulted with appropriate experts including experts in penology, medicine, and ethics, and provided his/her approval of such research in writing.
- 4.4. Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject.
 - a. 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 one of the following consultations have taken place:
 - i. For research that is conducted or supported by HHS, the Secretary of HHS or his/her designee 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.

- ii. For research that is not conducted or supported by HHS, the Vice Chancellor for Research has consulted with appropriate experts, including experts in penology, medicine, and ethics, and provided his/her approval of such research in writing.

5. Criteria for IRB Approval

In order to approve research involving prisoners as subjects, the CUNY UI-IRB must find and document that, in addition to the criteria outlined in [CUNY HRPP Policy: Criteria for IRB Approval](#), research involving prisoners as subjects meets the following criteria:

- 5.1. The research under review represents one of the categories of research outlined in section 4 above.
- 5.2. 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.
- 5.3. The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers.
- 5.4. 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 (PI) 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.
- 5.5. The information is presented in language which is understandable to the subject population.
- 5.6. 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.
- 5.7. Where the Board finds there may be a need for follow-up examination or care of participants after the end of their participation, 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.

6. Epidemiological Studies

Certain epidemiological studies qualify for a waiver of requirements outlined in section 4 above. To qualify for this waiver, the epidemiological study must meet BOTH of the following criteria:

1. The sole purposes of the study are:
 - a. To describe the prevalence or incidence of a disease by identifying all cases; OR
 - b. To study potential risk factor associations for a disease.
2. The CUNY UI-IRB approves the research, and documents that:
 - a. The research meets the criteria in sections 5.2-5.7 above;
 - b. The research presents no more than minimal risk and no more than inconvenience to the prisoner-subjects; AND
 - c. Prisoners are not a particular focus of the research.

7. Certification of HHS Conducted or Supported Research

7.1. When a CUNY UI-IRB approves research involving prisoners as research subjects, which is conducted or supported by the HHS, CUNY Office of Research shall certify to the Secretary of the HHS in writing that the criteria listed in sections 4 and 5 above, or section 7 when applicable, have been fulfilled.

7.2. The certification must include the following:

- Name and address of the CUNY institution
- OHRP issued Federal-wide Assurance number
- IRB Registration number
- Protocol title and CUNY protocol ID
- Name and Title of the Principal Investigator
- Attachment: CUNY UI-IRB application form(s)
- Attachment: CUNY UI-IRB approved consent document(s)
- Attachment: CUNY UI-IRB approved protocol, when applicable
- Attachment: HHS grant application or protocol
- Attachment: CUNY UI-IRB approval letter.

7.3. HHS conducted or supported research involving prisoners as subjects may not proceed until OHRP issues its approval in writing on behalf of the HHS Secretary.

References

1. [Code of Federal Regulations, Title 45 – Public Welfare DHHS, Part 46 – Protection of Human Subjects](#)
2. [U.S. Department of Health & Human Services. OHRP Guidance on the Involvement of Prisoners in Research. May 23, 2003.](#)
3. [Federal Register Volume 68, Number 119 \(Friday, June 20, 2003\)](#)