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 IRB prior to its initiation.

   3.1. Research involving prisoners cannot be exempt from IRB review; therefore, [CUNY HRPP Procedures: Human Subjects Research Exempt from IRB Review](#) DOES NOT apply.

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

      3.2.1. 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.

   3.3. 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:

      3.3.1. 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.

      3.3.2. 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. **When a Non-Prisoner Subject Becomes a Prisoner**

6.1. This policy applies whenever any human subject in a research protocol becomes a prisoner at any time during the study.

6.2. The PI is responsible for:

   a. Immediately informing the IRB if a research subject who was not previously a prisoner becomes a prisoner while participating in the research;
b. Discontinuing any research related interventions or interactions with, and collecting identifying information about, the now prisoner subject, except in circumstances in which the investigator asserts that it is in the best interest of the subject to remain in the research study while incarcerated; AND

c. Advising the IRB as to whether the PI and the subject wish the subject to continue participation in the research.

6.3. If the PI and the subject wish the now prisoner subject to continue participating in the research, the CUNY UI-IRB must re-review the protocol, and determine whether the involvement of the now prisoner subject meets all of the requirements of this policy.

6.4. If the IRB determines that the research does not meet all of the requirements of this policy, the now prisoner subject must be withdrawn from the research. Appropriate measures agreed upon by the PI and the IRB must be implemented to ensure adequate protection of the health and welfare of the subject, as they relate to the subject's prior participation in research.

7. 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:

a. The sole purposes of the study are:
   i. To describe the prevalence or incidence of a disease by identifying all cases; OR
   ii. To study potential risk factor associations for a disease.

b. The CUNY UI-IRB approves the research, and documents that:
   i. The research meets the criteria in sections 5.2-5.7 above;
   ii. The research presents no more than minimal risk and no more than inconvenience to the prisoner-subjects; AND
   iii. Prisoners are not a particular focus of the research.

8. Certification of HHS Conducted or Supported Research

8.1. When a CUNY UI-IRB approves research involving prisoners as research subjects, which is conducted or supported by the HHS, the Office of the Vice Chancellor for 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.

8.2. The certification must include the following:
   a. Name and address of the CUNY institution
   b. OHRP issued Federalwide Assurance number
   c. IRB Registration number
   d. Protocol title and CUNY protocol ID
e. Name and Title of the Principal Investigator
f. Attachment: CUNY UI-IRB application form(s)
g. Attachment: CUNY UI-IRB approved consent document(s)
h. Attachment: CUNY UI-IRB approved protocol, when applicable
i. Attachment: HHS grant application or protocol
j. Attachment: CUNY UI-IRB approval letter

8.3. 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


3. Federal Register Volume 68, Number 119 (Friday, June 20, 2003)