	UNIVERSITY RESEARCH POLICY: Research Involving Prisoners as Research Subjects			
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Policy Statement

This policy describes the policy and procedures for Institutional Review Board (IRB) review of research involving prisoners as research subjects. Research involving prisoners requires compliance with the federal regulations at 45 CFR 46 Subpart C (“Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects”)

Reason for Policy

Research with prisoners is governed by federal regulations that classify prisoners as a “vulnerable population” (45 CFR 46 Subpart C) and are considered to have diminished autonomy, as their ability to make an informed and voluntary decision to participate in research is compromised.

Entities Affected By This Policy

This policy applies to all faculty, staff, and students of the university conducting human subjects research involving prisoners as research subjects; the IRB committee members and chairs; Research Integrity office staff.

Who Should Read This Policy

- Faculty, staff, and students of the university engaged in human subjects research subject to IRB review and oversight
- New and re-appointed IRB committee members
- New and re-appointed IRB committee co-chairs
- Research Integrity office staff


Responsibilities

Responsible Party	List of Responsibilities
Designated reviewers	Apply this policy when conducting reviews of IRB applications involving prisoners as research subjects.
Lehigh University faculty, staff, and students submitting human subjects research for IRB review	Read, understand, and follow this policy when preparing applications involving prisoners as research subjects for submission to the IRB. Read, understand, and follow this policy when conducting human subjects research involving prisoners as research subjects.
Research Integrity office staff	Process IRB reviews and apply this policy when research involves prisoners as research subjects.

Principles

For research involving prisoners as research subjects, the IRB will approve the conduct of the research only if it finds that the research meets the regulatory criteria for approval addressed under the federal regulations at 45 CFR 46 Subpart C (“Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects”).

A prisoner is defined as “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

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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)

Procedures

Initial Screening

Upon acceptance of a complete package, the Research Integrity office staff makes a preliminary determination as to whether this policy applies to the study.


Review

Research involving prisoners that is federally funded or which is conducted in a federal prison will be reviewed by a convened IRB committee which includes at least one member who is a prisoner or a prisoner representative with appropriate background and experience to serve in that capacity. All other studies involving prisoners will include a prisoner representative as a consultant. This includes initial review, continuing review, full-board modifications, and reportable unexpected or unanticipated problems.

- Modifications that would otherwise be approvable by expedited review can be expedited (with the exception of DoD funded studies) as long as the prisoner representative receives a copy of the modification and concurs that it does not adversely affect the prisoners.

The IRB will approve the research only if it finds and documents that:

1. The research meets one of the regulatory criteria for approval addressed under 45 CFR §46.306 (a)(2); that is the research is a study of:
 - a. 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;
 - b. 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;
 - c. 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 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; or
 - d. 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. Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, and quality of food, amenities and opportunity for earnings in the prison, are not of such 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;
3. The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;

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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 provides to the IRB 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 research project;
5. The information is presented in a language which is understandable to the subject population;
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;
7. Where the IRB finds there may be a need for follow-up examination or care of subjects 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 subjects of this fact.

Federally Funded Research Involving Prisoners as Research Subjects

If a study utilizing prisoners as research participants is federally funded, the Director of Research Integrity or their designee will send a letter to the Office for Human Research Protections (OHRP) indicating it has approved a study that will include prisoners, the category the study fits into as well as how the study satisfies the six criteria noted under the regulations. A research study is not permitted to commence for DHHS supported research until written approval is received from OHRP on behalf of the DHHS Secretary under the provisions of 45 CFR §46.306(a)(2).

Subjects Who Become Prisoners After Study Enrollment

If a subject becomes a prisoner after enrollment in a research study not approved by the IRB to include prisoners as research subjects, the investigator should notify the IRB immediately. Either the prisoner-subject must be withdrawn from study participation; or the IRB must, at the earliest opportunity, re-review the research protocol and consent form in accordance with the listed requirements for IRB approval of research including prisoners as subjects. The IRB can either (a) approve the involvement of the prisoner-subject in the research or (b) determine that this subject must be withdrawn from the research. Note that if the subject-prisoner is withdrawn from study participation, s/he must be fully informed of the reason for such action.

Web Address For This Policy


[Lehigh University IRB website](#) (IRB Standard Operating Procedures and Policies)

Related Resources

University Policies and Documents Lehigh University IRB Glossary
External Resources Code of Federal Regulations 45 Part 46, Protection of Human Subjects Code of Federal Regulations 45 Part 46, Protection of Human Subjects, Subpart C

Contacts

Subject Matter	Office Name	Telephone Number	E-mail/Web Address
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Policy Clarification and Interpretation	Senior Research Integrity Specialist	610-758-2871	https://research.cc.lehigh.edu/contact-us-0
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