

**Nova Southeastern University
Office of Grants and Contracts
Institutional Review Board
Policies and Procedures**

**Research with Prisoners
Effective 11/08/2007
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Purpose:

To establish policy and procedures for the review and approval of research that involves prisoners and to provide researchers with information on the types of research that are permitted.

Definitions:

1. Minimal risk: is 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. This definition differs slightly from the definition of minimal risk applied to studies that do not involve prisoners. For the latter studies, federal regulations (45 CR 46.102) define minimal risk as being "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."
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 that provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

Policy:

A.

Because prisoners may be under constraints due to their incarceration that could affect their ability to make a truly voluntary and un-coerced decision about whether or not to participate as subjects in research, researchers must adhere to additional safeguards for the protection of prisoners.

IRB approval of studies involving prisoners may be given if such studies fall under one or more of the four allowable categories described in federal regulations (45 CFR 46.306(a)(2)). It is not sufficient that the research just include one of these items, the study must be limited to research in one or more of these categories. Researchers are advised to review these categories closely and are also advised to recommend the type of category they believe their research falls under.

1. The study is 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 subject.

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2. The study is 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 subject.
3. The study is related to 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 of Health and Human Services (through OHRP) has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of his/her intent to approve such research.
4. The study is on 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 of Health and Human Services (through OHRP) has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of his/her intent to approve such research.

Another category of research that may be permissible was added by recent federal regulations. This pertains to epidemiological research which is defined as “public health” research that focuses on a particular condition or disease in order to (i) describe its prevalence or incidence by identifying all cases, including prisoner cases, or (ii) study potential risk factor associations, where the human subject may include prisoners in the study population but not exclusively as a target group, provided that the study presents no more than minimal risk and no more than inconvenience to the subject.

B.

In addition to all other responsibilities prescribed for the IRB, the Board shall review research covered by this subpart and approve such research only if it finds that:

- the research under review represents one of the categories of research permissible under 45 CFR 46.306(a)(2), or the permissible categories of epidemiologic research.
- 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;

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- the risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;
- 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 justification in writing to the Board 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;
- the information is presented in language that is understandable to the subject population;
- 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; and
- 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.

Please note that if the prisoner also falls under the definition of a child then the regulations related to research with children also apply.

With respect to research involving prisoners, the IRB shall also meet the following specific requirements:

- A majority of the Board (exclusive of prison members) shall have no association with the prison(s) involved, apart from their membership on the Board
- At least one member of the Board shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one Board, only one Board need satisfy this requirement.

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References:

45 CFR 46.303
45 CFR 46.304
45 CFR 46.305
45 CFR 46.306
Federal Register Vol.68; No. 119, Epidemiological Waiver

Procedures:

1. Research involving prisoners will be reviewed by the full IRB.
2. At least one member of the Board shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one Board, only one Board need satisfy this requirement.
3. The Board will review the study to determine whether the study meets the federal requirements noted in Section B of this policy and only approve studies that meet all requirements.
4. The Board will determine which federally permitted study type or types the approved study consists of and will notes this in the minutes.