

Prisoners are considered a vulnerable population because of their limited choice environment, and are entitled to additional protections when participating in research. Federal regulations restrict the type of research to be conducted with this population to biomedical or behavioral research in 5 allowable categories. Additional requirements apply to IRB review of prisoner research, and some funded research may require a federal review prior to initiation.

1.0 Applicability.

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 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.

1.1 Applicable.

The definition of 'prisoner' applies to individuals in any kind of penal institution (i.e., prison, jail, juvenile offender facility), who are restricted from leaving the institution (i.e., convicted felons, untried persons who are detained pending judicial action). Some examples would include:

- individuals detained in a residential facility for court-ordered substance abuse treatment as a form of sentencing or alternative to incarceration
- individuals with psychiatric illnesses who have been committed involuntarily to an institution as an alternative to a criminal prosecution or incarceration
- parolees detained in a treatment center as a condition of parole.

1.2 Not applicable.

The regulatory definition of 'prisoner' would not apply to:

- individuals residing in the community who are receiving non-residential court-ordered substance abuse treatment
- individuals voluntarily admitted to an institution for treatment of psychiatric illness, or who have been civilly committed to non-penal institutions for treatment because their illness makes them a danger to themselves or others
- persons (including parolees) living in the community and sentenced to community-supervised monitoring
- probationers and individuals wearing monitoring devices (these persons may sometimes be considered prisoners depending on the particular circumstances of the subject population).

1.3 Research participants as incidental prisoners.

Individuals may become incarcerated or otherwise meet the regulatory definition of a 'prisoner', while currently enrolled in a research project. In that situation, an investigator must notify the IRB, and suspend all research interactions and interventions with the now-incarcerated-prisoner-participant immediately. An exception may be made if the investigator asserts that it is in the best interests of the participant to remain in the research study.

If the IRB had not previously reviewed and approved the research to involve prisoners as participants, it must review it under these requirements, unless the participant who is now a prisoner is permanently withdrawn from the study. If an investigator anticipates the likelihood that some research participants may become prisoners during the course of a study, they may request that the IRB prospectively review the protocol as a prisoner research project.

2.0 Permissible categories of research involving prisoners.

In order to approve research involving prisoners, the IRB must determine that the research falls into one of the permissible categories:

2.1 Incarceration and criminal behavior (45 CFR 46.306(a)(2)(i)).

Research that involves study of the possible causes, effects, and processes of incarceration, and of criminal behavior are applicable to this category. The research must not involve more than minimal risk, and no more than inconvenience to subjects. Note that the definition of 'minimal risk' for a prisoner population varies from that used with other groups.

2.2 Prisons as institutions, or prisoners as incarcerated persons (45 CFR 46.306(a)(2)(ii)).

Research that involves the study of prisons as institutional structures, or prisoners as incarcerated persons is applicable to this category. The research must not involve more than minimal risk, and no more than inconvenience to subjects. Note that the definition of 'minimal risk' for a prisoner population varies from that used with other groups.

2.3 Conditions affecting prisoners as a class (45 CFR 46.306(a)(2)(iii)).

Research that involves the study of conditions that particularly affect prisoners as a class (i.e., vaccine trials and other research on hepatitis which is more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction and sexual assaults) are applicable to this category. Research in this category supported by federal funding may require federal consultation and review prior to initiation of the study (see 6.0 below).

2.4 Practices to improve the health or well-being of subjects (45 CFR 46.306(a)(2)(iv)).

Research that involves the study of practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of subjects are applicable to this category. When the research requires assignment of prisoners to control groups which may not benefit, federally funded projects may require a process of federal consultation and review prior to initiation of the study (see 6.0 below).

2.5 Epidemiological research.

Epidemiological research may also be applicable to this category. This would include: research conducted with the sole purpose of describing the prevalence or incidence of a disease by identifying all cases, and research on potential risk factor associations for a disease.

3.0 IRB composition and review.

When reviewing research involving prisoners, additional federal requirements for IRB composition and review apply.

3.1 Prisoner representative.

In addition to the standard requirements for IRB composition (see *4.1 IRB Membership*), the IRB must include a prisoner or prisoner representative as a member when reviewing research involving prisoners. This individual should have the appropriate background and experience to serve in that capacity, with a close working knowledge and understanding of prison conditions from the prisoner's perspective. A majority of the IRB members (exclusive of the prisoner representative) shall have no association with the prison(s) involved in the research.

3.3 IRB review.

The IRB reviews new and continuing research involving prisoners at a convened meeting where a prisoner or prisoner representative is present as a voting member unless the research qualifies for expedited review. The expedited method of review may be used, provided that the research meets the definition of 'minimal risk' for a prisoner population, qualifies for expedited review, and a prisoner representative serves as one of the reviewers. Refer to *7.3 Expedited Review* for more information. The exemption categories do not apply to research involving prisoners.

4.0 Additional determinations for IRB approval of prisoner research.

In order to approve research involving prisoners, the IRB must determine that the project meets all the standard criteria for approval (see *7.2 Criteria for IRB Approval*), as well as the following additional criteria:

- 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;
- the risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;
- procedures for the selection of participants 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 Board justification in writing for following some other procedures, control participants 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 which is understandable to the participant 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 IRB 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.

In order to make these findings, the IRB must be familiar with the specific conditions in the local prison(s) or jail site(s) that are pertinent to subject protections. Information on local context may be obtained from membership of the IRB or consultants.

5.0 Informed consent requirement.

Investigators must obtain the legally effective informed consent of prisoners prior to their participation in research, unless the requirement has otherwise been waived or altered by the IRB. Refer to *9.1 Consent Process*, *9.2 Documentation of Informed Consent*, and *9.3 Waiver or Alteration of Informed Consent Requirements* for more information. However, even when consent is waived or altered, prisoners must be informed in advance that their research participation will have no effect on their parole (if such notification is relevant). Prisoners may not be involved in emergency research where the IRB has waived the requirement for informed consent.

6.0 Federally funded prisoner research.

Prisoner research supported by the US Dept. of Health and Human Services (HHS) is subject to additional requirements prior to initiation.

6.1 IRB certification to HHS.

The IRB must certify to HHS, through the Office of Human Research Protections (OHRP), that the IRB has reviewed the prisoner research, and made the additional required findings, as outlined in 2.0 and 4.0 above. HRPP staff will forward documentation of the certification to OHRP that includes:

- a copy of the research protocol, and any attachments
- any relevant HHS grant application
- any other information requested or required by the IRB for review
- a letter of certification including: NDSU's Federal Wide Assurance number, IRB Registration number, the date of the IRB meeting(s) in which the protocol was reviewed, a brief chronology that includes the date of IRB review, and the date of prisoner review (if not done at initial review).

The research may proceed only after NDSU has received a letter from OHRP authorizing the involvement of prisoners in the research.

6.2 OHRP consultation and determination.

HHS supported prisoner research in several categories (2.3 and 2.4 above) may also require a federal consultation process. OHRP (on behalf of HHS) will consult with appropriate experts, and where applicable, publish a notice of intent to approve such research in the Federal Register. Such research may proceed only after receipt of a letter of authorization from OHRP.

DEFINITIONS:

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.

Informed consent: the voluntary agreement of a participant, or their legally authorized representative, to take part in research, after being provided with sufficient information about the study, in a language and terminology understandable to them, and sufficient opportunity to consider their decision.

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.

REFERENCES:

[45 CFR 46, Subpart C](#) Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects
[45 CFR 46.116](#) General requirements for informed consent
OHRP FAQs: [Prisoner Research](#)

RELATED FORMS:

IRB Protocol Form
Prisoners in Research Attachment form

RELATED HRPP SECTIONS:

4.1 IRB Membership
7.2 Criteria for IRB Approval
9.1 Consent Process
9.2 Documentation of Informed Consent
9.3 Waiver or Alteration of Informed Consent Requirements