

RESEARCH INVOLVING SPECIAL POPULATIONS: PRISONERS

| | | | | | | | |
|---|------------|---|--|------------------------|----------------|-----------------------------|------------|
| SOP #: | 502 | VERSION #: | 1 | EFFECTIVE DATE: | 5/1/09 | SUPERSEDES DOCUMENT: | / / |
| THIS POLICY PERTAINS TO: | | | ALL RESEARCH SUBMITTED TO THE IRB | | | | |
| RESPONSIBILITY FOR EXECUTING POLICY: | | ASSOCIATE VICE PRESIDENT FOR RESEARCH AND ECONOMIC DEVELOPMENT; IRB CHAIRPERSON, IRB VICE CHAIRPERSON, IRB MEMBERS | | | | | |
| LAST REVIEWED ON: | | / / | | RESULTS: | REVISED | | |
| APPROVAL AUTHORITY: | | Associate Vice President for Research and Economic Development | | | | | |
| APPROVED BY: | | | | | DATE: | | / / |

1. POLICY

The special vulnerability of prisoners makes consideration of involving them as research subjects particularly important. Prisoners may be under constraints because of their incarceration, which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research. To safeguard their interests and to protect them from harm, special ethical and regulatory considerations apply for reviewing research involving prisoners.

Therefore, if a protocol involves the use of prisoners as subjects, both the general IRB Policies apply and the special ones outlined in this policy apply. The IRB may approve research involving prisoners only if these special provisions are met. If at some point while participating in a research project a participant becomes incarcerated, it is the responsibility of the Investigator to notify the UND IRB. The protocol will then be re-reviewed according to [45 CFR 46 Subpart C](#), or the participant-prisoner will be withdrawn from research.

2. SPECIFIC POLICY

2.1 Definitions

Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom authority has been delegated.

DHHS means the Department of Health and Human Services.

Prisoner means 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.

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.

2.3 Composition of Institutional Review Boards Where Prisoners are Involved [\(45CRF46.304\)](#)

In addition to satisfying the requirements in §46.107, an Institutional Review Board, carrying out responsibilities under this part with respect to research covered by this subpart, shall also meet the following specific requirements:

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.
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.

2.4 Additional duties of the Institutional Review Boards where Prisoners are Involved. [\(45CRF46.305\)](#)

If an Investigator indicates in the study submission that prisoners will participate in the research, or that subjects may reasonably be expected to be incarcerated at some time point during the study, the following additional requirements will apply to IRB review of the project:

1. If the research involving prisoners is neither conducted nor supported by DHHS then the IRB will include in its minutes that the research falls into one of the four categories of research 45 CFR 46.306(2)(A)-(D).
2. If the research involving prisoners is either conducted or supported by DHHS then the IRB will certify to the Secretary of DHHS, in such a manner as the Secretary may require, that the duties of the IRB under this section have been fulfilled. The IRB will include in its minutes that the research falls into one of the four categories of research 45 CFR 46.306(2)(A)-(D).

The IRB will review the proposed research to ensure one of the following four categories is applicable:

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 [\(45 CFR 46.306\(a\)\(1\)\(A\)\)](#).
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 [\(45 CFR 46.306\(a\)\(1\)\(B\)\)](#).
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 the Secretary 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 [\(45 CFR 46.306\(a\)\(1\)\(C\)\)](#).
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. 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 [\(45 CFR 46.306\(a\)\(1\)\(D\)\)](#).

2.5 Permitted research involving prisoners.

The IRB will then proceed to confirm that the following items are applicable [45 CFR 46.305\(a\)](#):

1. Any possible advantages accruing to the prisoner through his/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/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;
2. The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;
3. 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 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;
4. The information is presented in language which is understandable to the subject population;
5. 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 not effect on his or her parole;
6. Where the Board finds there may be a need for follow-up examinations 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, and
7. A data safety monitoring plan has been established to monitor participants.

2.6 When Subjects Become Prisoners During a Research Protocol

This policy applies whenever any human subject in a research protocol becomes a prisoner at any time during the protocol, *e.g.*, after the research has commenced. This is necessary because it is unlikely that review of the research and the consent document contemplated the constraints imposed by the possible future incarceration of the subject.

- If a subject becomes a prisoner after enrollment in research, the Principal Investigator is responsible for reporting this situation in writing to the IRB immediately.
- At the earliest opportunity after receiving the Investigator's notice or otherwise becoming aware of the prisoner status of a subject, the IRB should review the protocol again with a prisoner representative as a member of the IRB. The IRB should take special consideration of the conditions of being a prisoner.
- Upon this review, the IRB can either (a) approve the involvement of the prisoner-subject in the research in accordance with this policy or (b) determine that this subject must be withdrawn from the research.
- If involvement of the prisoner subject is approved, a special addendum to the consent document must be created that informs the subject of the impact incarceration may have on his or her continued participation.

3. RESPONSIBILITY

The IRB Coordinator is responsible for maintaining up-to-date review tools for review of research pertaining to vulnerable groups based on new and evolving applicable regulations and guidelines.

The IRB Chairperson and the IRB Coordinator are responsible for ensuring the IRB members are well versed in new and evolving regulations and guidelines pertaining to vulnerable populations.

The IRB Chairperson, IRB Coordinator, and/or IRB Secretary is responsible for selecting primary reviewers with appropriate expertise to conduct the reviews of such research, and for securing appropriate consulting expertise as needed for selected reviews.

The Primary Reviewer is responsible for conducting appropriate review of research planned for vulnerable populations, including an assessment of potential for coercion, in consultation with any appropriate experts and resources.

IRB Members are responsible for review of the research thoroughly enough to participate in the discussion at the convened IRB meeting.

4. APPLICABLE REGULATIONS AND GUIDELINES

The Belmont Report
45 CFR 46: Subpart C
45 CFR 46.305
45 CFR 46.122
21 CFR 56.111
OHRP IRB Guidebook

5. ATTACHMENTS

SC 502-A Checklist for Research Involving Prisoners

6. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

| Who | Task |
|--|--|
| <i>IRB Coordinator</i> | Maintain and update checklist to conform to applicable regulations and guidelines. |
| <i>IRB Chairperson, IRB Coordinator, IRB Secretary</i> | Select appropriate Primary Reviewers or obtain expert consultant. |
| <i>IRB Secretary</i> | Provide Primary Reviewers with appropriate checklist. |
| <i>Primary Reviewers</i> | Complete checklist during review of research and present recommendations at convened meeting. Confirm that proposal has informed consent and assent documents as appropriate. |