

<b>SOP: 503</b> <b>Effective Date: 07/01/2019</b>	<b>RESEARCH INVOLVING PRISONERS</b>	<b>Supersedes Document Dated: 12/05/2017</b>
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## 1. POLICY

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. Therefore, the Institutional Review Board (IRB) is required to provide additional safeguards for the protection of prisoners involved in human subject research activities.

These procedures apply to all research involving prisoners as defined by 45 CFR 46 Subpart C.

## 2. DEFINITIONS

- 2.1** *Informed Consent.* A person's affirmative agreement to participate in a research study after achieving an understanding of what is involved.
- 2.2** *Minimal Risk.* 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** *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.

Common examples of the application of the definition of prisoner are as follows:

- 2.3.1** Individuals who are detained in a residential facility for court-ordered substance abuse treatment as a form of sentencing or alternative to incarceration are prisoners; however, individuals who are receiving non-residential court-ordered substance abuse treatment and are residing in the community are not prisoners.
- 2.3.2** Individuals with psychiatric illnesses who have been committed involuntarily to an institution as an alternative to a criminal prosecution or incarceration are prisoners; however, individuals who have been voluntarily admitted to an institution for treatment of a psychiatric illness, or who have been civilly committed to nonpenal institutions for treatment because their illness makes them a danger to themselves or others, are not prisoners.
- 2.3.3** Parolees who are detained in a treatment center as a condition of parole are prisoners; however, persons living in the community and sentenced to community-supervised monitoring, including parolees, are not prisoners.

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2.3.4 Probationers and individuals wearing monitoring devices are generally not considered to be prisoners; however, situations of this kind frequently require an analysis of the particular circumstances of the planned subject population.

**2.4** *Risk.* The possibility of harm to a subject in a research study.

**2.5** *Secretary.* The Secretary of the Department of Health and Human Services (DHHS).

### **3. PROCEDURES**

**3.1** Research that would otherwise qualify for exemption from IRB review is not exempt when the research involves prisoners.

**3.2** Due to the vulnerability of prisoners, DHHS strongly recommends that research involving prisoners be reviewed by the full convened IRB. However, if the research is reviewed under the expedited review procedure, the IRB Member(s) reviewing the research must include a prisoner or prisoner representative.

**3.3** An IRB may only approve research projects involving prisoners if the research falls under one of the following categories:

3.3.1 Study of possible causes, effects and processes of incarceration, and of criminal behavior, provided that the study present no more than minimal risk or inconvenience to subjects;

3.3.2 Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study present no more than minimal risk and no more than inconvenience to the subjects;

3.3.3 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); or

3.3.4 Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject.

**3.4** In addition to all other responsibilities prescribed for the Institutional Review Boards, the IRB shall review research involving prisoners and approve such research only if it finds that:

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- 3.4.1 The research under review represents one of the categories of research permissible under 3.3 of this document;
- 3.4.2 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;
- 3.4.3 The risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;
- 3.4.4 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 particular research project;
- 3.4.5 The information is presented in language which is understandable to the subject population;
- 3.4.6 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; and
- 3.4.7 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.

### **3.5 Research Conducted or Supported by DHHS – Additional Requirements**

- 3.5.1 Research involving prisoners that is conducted or supported by DHHS must fulfill the following requirements before it is conducted:
  - (a) The institution engaged in the research must certify to the Secretary (via the Office for Human Research Protections (OHRP)) that the IRB designated under its assurance of compliance has reviewed and approved the research under this SOP; and

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- (b) The Secretary (through OHRP) must determine that the proposed research falls within the categories of research permitted to involve prisoners; and
- (c) The Secretary (through OHRP) must review and provide written approval before any research activities may begin, including screening and enrollment; and
- (d) If the research falls under Section 3.3.3, the study may proceed only after the Secretary (through OHRP) has consulted with the appropriate experts including experts in penology, medicine and ethics, and published notice, in the Federal Register, of his/her intent to approve such research.
- (e) If the research falls under Section 3.3.4, and 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 (through OHRP) has consulted with the appropriate experts including experts in penology, medicine and ethics, and published notice, in the Federal Register, of his/her intent to approve such research.

3.5.2 Investigators must provide any additional documents or materials required for certification to the Secretary (through OHRP).

### **3.6 Minors**

3.6.1 Research involving prisoners who are minors (e.g., an individual detained in juvenile detention center) must also be reviewed and conducted in accordance with SOP 502: Research Involving Children.

### **3.7 Additional Approvals and Permissions**

3.7.1 For research within a penal institution or other facility in which prisoners will be subjects, the Investigator must obtain written permission from the institution or facility and submit that with the protocol application to the IRB.

3.7.2 Indiana Department of Corrections

- (a) All requests for access to offender or juvenile records for research purposes shall be made to the director of planning services in written form. Such requests shall include the name of the agency or organization performing the research, the names of the persons directly responsible for the following:

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- (i) Conducting such research.
  - (ii) The purpose of such research.
  - (iii) How the research is to be performed.
  - (iv) What measures will be taken to assure the proper protection of classified information.
- (b) Approval of such requests will then be granted or denied consistent with provisions of Indiana Code 4-1-6-8.6 and department procedures.

3.7.3 Federal Bureau of Prisons. The Federal Bureau of Prisons places special restrictions on research that takes place within the Bureau of Prisons under 28 CFR 512. This rule specifies additional requirements for prospective researchers to obtain approval to conduct research within the Bureau of Prisons and responsibilities of Bureau staff in processing proposals and monitoring research projects.

#### **4. RESPONSIBILITY**

##### **4.1 Investigator Responsibility**

- 4.1.1 For any new protocol application in which prisoners will be the target population or may make up part of the subject population, the Investigator must obtain approval from the IRB prior to recruiting or enrolling any prisoners in the study.
- 4.1.2 Investigators proposing to conduct research with prisoners must complete and submit the appendix with their protocol application.
- 4.1.3 For research within a penal institution or other facility in which prisoners will be subjects, the Investigator must obtain written permission from the institution or facility and submit that with the protocol application to the IRB.
- 4.1.4 For research conducted within the Federal Bureau of Prisons or Indiana Department of Corrections, the Investigator must obtain approval from the Bureau or Indiana Department of Corrections prior to initiating the recruitment of subjects and supply a copy of the approval to the IRB.
- 4.1.5 When an enrolled research subject becomes a prisoner and the research was not previously reviewed and approved for the inclusion of prisoners by the IRB (and DHHS, as appropriate), the Investigator must promptly inform the IRB in writing of the change in subject's status.

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- (a) All research interactions and interventions with, and obtaining identifiable private information about, the prisoner-subject must cease until the protocol has been reviewed and approved for the inclusion of the prisoner-subject.
- (b) If research interactions and interventions or obtaining identifiable private information will not occur during the incarceration period, or if the Investigator wishes to withdraw the now prisoner-subject from the research, the Investigator must notify the IRB of such in writing.
- (c) If continued participation of the prisoner-subject is needed, the Investigator must submit a revision request for the protocol requesting inclusion of prisoners in the research and address the requirements in Section 3.4, including protocol specific information justifying each requirement. The revision request will be reviewed by the convened IRB (or by the IRB Chair or expedited reviewer, if the study is otherwise eligible for expedited review).

## **4.2 IRB Responsibility**

### **4.2.1 Composition of the IRB**

The following IRB composition requirements must be met for all types of review for protocols involving prisoners as subjects: initial review, review of amendment requests, continuing review, or in the event a subject becomes a prisoner while participating in the research. Review of reports of noncompliance, and unanticipated problems and adverse events will be conducted according to the procedures documented in those SOPs.

- (a) 4.2.1.1 A majority of IRB Members (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the IRB.
- (b) 4.1.1.2 At least one IRB Member shall be a prisoner, former prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity.

- 4.2.2 For research involving prisoners, the IRB and HRPP staff are responsible for conducting initial review, continuing review, review of amendment requests, review of reports of noncompliance, and reports of unanticipated problems and adverse events in accordance with the procedures documented in this SOP as well as all applicable Purdue University policies and HRPP procedures.

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4.2.3 Should a subject become a prisoner (see section 4.1.5 above) and the research protocol has not yet been reviewed and approved by the IRB and DHHS for compliance with this SOP, where the Investigator asserts that it is in the best interests of the subject to remain in the research study while incarcerated, the subject may continue to participate in the research until the requirements of this SOP are satisfied. The IRB Chair or his/her designee can make that determination and report it to the IRB at the next scheduled meeting.

## **5. APPLICABLE REGULATIONS AND GUIDELINES**

45 CFR 46 Subpart C

28 CFR 512

Title 210. Department of Correction, Article I. General Provisions IAC 1-6-7

[OHRP, Prisoner Involvement in Research \(2003\)](#)

[OHRP Guidance, FAQ on Prisoner Research](#)

## **6. REFERENCES TO OTHER APPLICABLE SOPs**

302 Initial Review

304 Continuing Review

305 Amendment Requests

502 Research Involving Children