

 <b>Research Integrity Office</b>	<b>Human Research Protection Program</b> Regulatory Sheet	
Title: Prisoner Research	Date Effective 4/21/2008	Supersedes P&P dated: N/A
	Identification #	Page 1 of 6

## Background

The federal regulations governing human subjects in research 45 CFR 46, Subpart C provide additional safeguards for the protection of research subjects who are prisoners because the constraints associated with incarceration may affect the individual's ability to make a truly voluntary and uncoerced decision regarding participation in research.

It is impossible to ignore the historical exploitation of prisoners and their current misgivings about the biomedical research enterprise. Prisoners are particularly vulnerable to exploitation not only because of their low socioeconomic status, but also due to the realities of prison life. At OHSU, we are committed to the acquisition of voluntary informed consent and the protection of privacy. We believe it is critical that a choice between research participation and nonparticipation is not simply a desperate action to obtain treatment.

## Authority

45 CFR 46 Subpart C, Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects

28 CFR 512.10-512.21 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.

OHRP Guidance Document: "OHRP Guidance on Involvement of prisoners in Research," May 23, 2003. [http:// www.hhs.gov/ohrp/humansubjects/guidance/prisoner.htm](http://www.hhs.gov/ohrp/humansubjects/guidance/prisoner.htm)

OHRP Informal 45 CFR 46 Subpart C Guidance, Report of the Subpart C Subcommittee to SACHRP, April 18, 2005.

Oregon Administrative Rules: Department of Corrections Research Proposals 291-035-0005 through 291-035-015

Oregon Administrative Rules: Department of Corrections Health Services 291-124-0080  
Oregon Revised Statute 421.085 Experimentation on inmates prohibited; inmate's rights to judicial restraint of violation; action for damages.

## Scope

This policy applies to all human subjects' research that involves subjects who are prisoners at the time of enrollment in the research or who become prisoners after being enrolled in the research.

## I. Policy

- A. When a protocol involves the use of prisoners as subjects, both the general OHSU IRB policies and procedures apply as well as the additional rules as determined by federal, state, county, and local regulations.
- B. The OHSU IRB must review all research in which prisoners are the target population, the subject is a prisoner at the time of enrollment, or when a currently enrolled subject becomes incarcerated and research interventions and interactions would occur during the incarceration period or identifiable private information will be obtained during the incarceration period.
- C. The exemptions at 45 CFR 46.101(b) do not apply to research involving prisoners.
- D. The OHSU IRB will not issue a waiver of consent for participants who are the subject of this policy.
- E. When a prisoner is a minor (e.g., an adolescent detained in a juvenile detention facility is a prisoner), the OHSU IRB policy regarding children in research will also apply.
- F. OHSU IRB-approved federally-funded research will be submitted for OHRP certification and while OHRP certification is not mandatory for non-DHHS supported research, it is the policy of the OHSU IRB to require investigators to abide by the OHRP certification requirements as stated above.
- G. In addition to the requirements of 45 CFR 46 Subpart A, a protocol involving prisoners must meet seven criteria. The **Additional Protocol Requirements** are as follows:
  1. The research under review represents **one** of the following categories of research permissible under [45 CFR 46.306\(a\)\(2\)](#):
    - a. A 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 participants.
    - b. A 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 participants.
    - c. Research on conditions particularly affecting prisoners as a class (e.g., 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 DHHS (through OHRP) 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.
    - d. 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 of DHHS (through OHRP) 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.
  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 prisoner is impaired;
  3. The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;
  4. 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 IRB 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;
  5. The information is presented in language that 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; and

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<sup>1</sup>.

## I. Procedure

### A. Principal Investigator

#### i. Inclusion of Prisoners in a Study

- a. It is the responsibility of the PI to plan for the inclusion of prisoners in research, with specific attention paid to the seven (7) required additional findings as noted in subsection I.F of this policy.
- b. In order to conduct any research in a correctional institution, the PI must seek and receive authority from that institution to continue the research. Questions will need to be asked of the prison or county jail authority or medical authority in regard to the feasibility of the inmates continued participation in the study.
- c. Prisoners have the fundamental right to decide whether or not to participate in research. Prisoners may not be participants in research without written informed consent.

#### ii. Research Participants with high likelihood of Arrest

- a. If the research population includes people who are likely to be jailed during a study, and whose participation the PI would like to continue, the study should be reviewed as prisoner research.
- b. This would include studies intending to enroll parolees, street people, addicts, and prostitutes because these individuals are more likely to be arrested than the general population.

#### iii. Subsequently Incarcerated Research Participant

- a. When a research participant is subsequently incarcerated, the PI and the OHSU IRB need to determine if the subsequently incarcerated person wants to continue in the protocol.
- b. If the incarcerated participant wants to continue in a trial that might positively affect the inmate's health and well-being, the PI should make efforts to do so.
- c. When a research participant is subsequently incarcerated and the study has not been reviewed under Subpart C, subpart A protections should be deemed to apply.
- d. It is the responsibility of the PI to report the involvement of a research subject who is or has become a prisoner, to the OHSU IRB, in writing, within 5 business days of being alerted to the subject's status as a prisoner.
- e. Subsection a above is not required if the study was previously approved by the OHSU IRB for prisoner participation.
- f. If the study was not previously reviewed and approved by the OHSU IRB in accordance with the requirements of Subpart C, all research interactions and interventions with the subject and/or collection of identifiable private information about the subject must cease until the requirements of the federal regulations have been satisfied with respect to the relevant protocol.
- g. **Exception:** if the PI asserts and the OHSU IRB Chairperson agrees that it is in the best interest of the subject to remain in the research study while incarcerated. In such cases, the subject may continue in the research until the requirements of the federal regulations are satisfied.

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<sup>1</sup> "Follow-up examination and care" should be interpreted to include any examination or care that is necessary after the end of a study or after a subject can no longer participate in a study due to release. The primary rationale for the Subcommittee's belief is its determination that the safety and welfare of all subjects would require consideration of both eventualities: release from custody during the study, or the ending of a study for persons who remain incarcerated.

- iv. Research with an Inmate in the Department of Corrections
  - a. Only research that has a therapeutic benefit to the inmate may be conducted in the Department of Corrections institutions of the State of Oregon.
  - b. Research projects conducted in the Department of Corrections must yield information to help the Department improve its effectiveness.
  - c. Individuals and agencies considering submitting research proposals should be aware that the proposal will be denied if the project would:
    - Expose any Department of corrections inmate, offender, or employee, with or without informed consent, to involvement in medical, psychiatric, or psychological experimentation or research within the meaning of ORS 421.085 or other statutes;
    - Require the disclosure of information protected by the provisions of ORS 179.505, 192.502, or other statutes (e.g. HIPAA, Genetic Privacy);
    - Pose appreciable hazard to the life or health of any human being, to state property, to the security, sound order, or discipline of any institution, or to the mission of the Department of Corrections or any of its functional units; or
    - Permit personal contact by other than Department of Corrections or law enforcement personnel with any current or former Department of Corrections inmate or offender, or with any other person concerning any current or former Department of Corrections inmate or offender, without the informed consent of the individual(s) concerned.
  
- v. Research with an Inmate in a County Jail
  - a. Research with an inmate in an Oregon County Jail is not subject to the rules of the Department of corrections; however, research is subject to federal rules and regulations
  - b. Before commencing research with an inmate in a county jail, you must contact the administration and obtain permission before submitting your proposal to the OHSU IRB.

**B. OHSU IRB Composition and Responsibilities**

- i. In order for the OHSU IRB to review and approve research that involves prisoners, it must meet the following requirements:
  - a. A majority of the IRB (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the IRB.
  - b. At least one member of the IRB must 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 IRB, then only one IRB needs to satisfy this requirement. If a prisoner representative is selected to serve on the IRB, the person must have a close working knowledge, understanding and appreciation of prison conditions from the perspective of a prisoner. Suitable individuals could include present or former prisoners; prison chaplains; prison psychologists, prison social workers, or other prison service providers; persons who have conducted advocacy for the rights of prisoners; or any individuals who are qualified to represent the rights and welfare of prisoners by virtue of appropriate background and experience.
  - c. The IRB must meet the special composition requirements for all types of review for the protocol: initial review, continuing review, review of protocol amendments, review of reports of adverse events or unanticipated problems involving risk to participants or others, or in the event an individual becomes a prisoner while participating in a research protocol.
  - d. The IRB must notify OHRP of any change in the IRB roster occasioned by the addition of a prisoner or a prisoner representative, if the approved OHSU IRB roster does not currently reflect this information.
  - e. The meeting minutes must state that the IRB discussed the seven additional required findings (see [Additional Protocol Requirements](#), above). Additionally, the minutes must reference that a majority of the IRB (exclusive of prisoner member/representative) has no association with the prison(s) involved and a qualified prisoner representative was present and voted on the protocol.

- ii. Review of studies involving Subsequently Incarcerated Research Participant
  - a. Additional review by the OHSU IRB to determine whether a subsequently incarcerated research participant should continue in a specific research protocol should include these questions:
    - How might the prisoner be subjected to coercion?
    - Are violations of confidentiality likely to occur and likely to affect the prisoner negatively? Could correctional health care providers be informed of the prisoner's study participation without informing the correctional authority?
    - Are there other issues on which this prisoner, because of his or her status as a subject of research might be vulnerable to negative and coercive forces?
  - b. The OHSU IRB should calculate the risk-benefit ratio in light of the conditions of confinement, of the particular inmate, but with the understanding that stopping a trial might also increase the risk to the inmate-subject.
  - c. In emergent situations, when it is necessary to decide whether or not the incarcerated participant could continue in the protocol, the OHSU IRB chair is empowered to decide, taking into account that this person has suddenly come within the category of a vulnerable subject. In such circumstances, the incarceration of a subject would be treated appropriately as a reportable even in the study, perhaps requiring a protocol change, approved either through expedited or full OHSU IRB review.

- iii. Requirements for conducting research in the Oregon State Department of Corrections
  - a. All proposals for research by investigators involving inmates as subjects must be submitted to the Oregon Department of Corrections Health Services Medical Director  
Steven Shelton MD, CCHP-A  
Oregon Department of Corrections  
2575 Center St. NE  
Salem, OR 97301

**iv. Expedited Review**

- a. Research involving prisoners may be reviewed through the expedited review procedure if the research is no more than minimal risk and meets the criteria for expedited review found at 45 CFR 46.110 and 21 CFR 56.110. However the definition of minimal risk for prisoner research at 45 CFR 46.303(d) differs from the definition of minimal risk for other research, contained in 45 CFR 46, subpart A, 45 CFR 46.102(i). Please refer to the definition section of this policy.
- b. The OHSU IRB is responsible for determining whether the research is minimal risk and whether the research is eligible for review through the expedited review procedure.
- c. If an expedited review procedure is used, the prisoner representative will still consult on the review.

**C. OHSU Research Integrity Office (ORIO) Responsibilities**

- i. Prisoner Certification Letter to OHRP
  - a. An institution that intends to conduct DHHS-supported research involving prisoners as subjects must certify to the Secretary (through OHRP) that the OHSU IRB has made the seven findings required under [45 CFR 46.305\(a\)](#), including the finding that the proposed research represents one of the permissible categories of research under [45 CFR 46.306\(a\)\(2\)](#).
  - b. ORIO must send OHRP a certification letter, to that effect, which should include the name and address of the institution and specific identification of the research protocol, including the relevant grant number.
  - c. The OHRP requires ORIO to submit a copy of the research proposal so OHRP can determine whether the proposed research involves one of the categories of research permissible under [45 CFR 46.306\(a\)\(2\)](#), and if so, which one. The term "research proposal" includes:
    - The OHSU IRB-approved protocol;
    - Any relevant DHHS grant application or proposal;
    - Any OHSU IRB application forms required by the IRB; and

- Any other information requested or required by the IRB to be considered during initial IRB review.
- d. OHRP also encourages the institution to include the following information in its prisoner research certification letter, to facilitate processing:
  - OHRP Assurance number;
  - OHSU IRB registration number; and
  - Date(s) of OHSU IRB Meeting(s) in which protocol was considered, including a brief chronology that encompasses the date of initial OHSU IRB review and date of Subpart C review.
- e. Prisoner research certification letters should be mailed to:
  - Attention: OHRP prisoner research contact person
  - Office for Human Research Protections
  - Department of Health and Human Services
  - The Tower Building
  - 1101 Wooton Parkway, Suite 200
  - Rockville, MD 20852

## Definitions

A **prisoner** is any individual involuntarily confined or detained in a penal institution encompassing<sup>2</sup>:

- 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.

An **inmate** according to Oregon law is any person under the supervision of the Department of Corrections who is not on parole, probation or post-prison supervision status.

**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.

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<sup>2</sup> Ankle bracelets/in home restrictions are considered incarceration. Mental and substance abuse facilities are considered incarceration if someone is mandated to attend in lieu of jail or prison; however, an individual in such a facility is not considered incarcerated if they voluntarily commit themselves. Probation and parole are usually not considered as incarceration. (The reason I believe this is because someone who is on house arrest may not be consenting voluntarily because their liberty is being restricted. Additionally, Under ORS 162.135 the definition of a correctional facility means any place used for the confinement of persons charged with or convicted of a crime or otherwise confined under a court order...this would lead me to believe someone under house arrest is in a correctional facility.)