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Prisoners in Research

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**Introduction**

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.

This Help Sheet is a supplement to:

- CHECKLIST HRP-308: Prisoners
- CHECKLIST HRP-309: Unexpected Incarceration
- SOP HRP-113: Unexpected Incarceration

You can help your review go smoothly by ensuring that your protocol and/or submission materials address all of the criteria in CHECKLIST HRP-308: Prisoners.

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**1. General Guidelines**

- A. The OHSU IRB must meet special review requirements for 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.

- B. If the research targets for enrollment people who are more likely than the general population to become prisoners during a study, and whose participation the PI would like to continue, the study should be reviewed as prisoner research. Examples of such populations may include parolees, street people, people who abuse drugs or alcohol, and people who engage in illegal activities.
- 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 prisoners.
- E. When a prisoner is a minor (e.g., an adolescent detained in a juvenile detention facility is a prisoner), policies and requirements regarding children in research will also apply.
- F. OHSU IRB-approved federally-funded research will be submitted for OHRP certification. Such studies must not enroll prisoners until confirmation of OHRP certification is received. This process can take several weeks following approval by the IRB.
- G. 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.

## **2. Definition of Prisoner**

- A. The definition of Prisoner includes:
  - 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.
- B. More challenging examples require a case-by-case analysis:
  - An individual who must wear an ankle bracelet to monitor house arrest is generally considered a prisoner, whereas an individual who wears an ankle bracelet for tracking purposes, but is not confined to a home or designated facility, is generally not considered a prisoner.
  - An individual on probation or parole is generally not considered a prisoner.
  - An individual committed by court order to a mental health or substance abuse facility in lieu of incarceration is considered a prisoner, but an individual who voluntarily commits him/herself to such a facility is generally not considered a prisoner.
  - An individual court-ordered to live in a “halfway house” or similar situation in which the person is not free to leave the facility without permission may be considered a prisoner.

## **3. 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. 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.

- F. **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.
- G. 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 event in the study.

#### **4. Research with an Inmate in the Oregon 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.
- D. All proposals for research by investigators involving inmates in the Oregon State Department of Corrections 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

#### **5. 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.

#### **6. 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(j). 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.

### **Additional Resources**

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.