

Vulnerable Populations – Prisoners

Background

Prisoners are considered to be vulnerable because the constraints of incarceration can affect their ability to make truly voluntary decisions to serve as research subjects. Further, the prison setting offers limited confidentiality and presents unique risks. For these reasons, federal regulations require additional protections for prisoners serving as research subjects. This document outlines primary requirements for IRB approval of research involving prisoners.

Definition of a Prisoner

Federal regulations define a prisoner 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 (45 CFR 46.303(c)).

The Office of Human Research Protections (OHRP) further clarifies that *individuals are prisoners if they are in any kind of penal institution, such as a prison, jail, or juvenile offender facility, and their ability to leave the institution is restricted. Prisoners may be convicted felons, or may be untried persons who are detained pending judicial action, for example, arraignment or trial.*¹

Examples of individuals who are prisoners include²

- 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.
- Other situations, such as those sentenced to wear electronic monitoring devices, are considered on a case-by-case basis.

Examples of individuals who are NOT typically prisoners include:

- Individuals who are receiving non-residential court-ordered substance abuse treatment and are residing in the community.

¹ Per OHRP [Prisoner Research FAQs](#)

² Per OHRP [Prisoner Research FAQs](#)

- Persons living in the community and sentenced to community-supervised monitoring, including parolees.
- Individuals who have been voluntarily admitted to an institution for treatment of a 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.

Although the individuals in the examples above are not considered to be prisoners, they are typically vulnerable and face unique risks that the IRB must consider.

IRB Review of Research Involving Prisoners

Except in very limited circumstances, all ISU research protocols involving prisoners are reviewed by the convened IRB (the “full-board”). An IRB member with expertise on the prison setting and the unique risks faced by prisoners (the Prisoner Representative) must be present during review.

Exceptions to the Full-Board Review Requirement

1. *Minor modifications* to previously-approved prisoner research may undergo “expedited” review by an IRB Chair, Vice-Chair, or Co-Chair. The reviewer should consult with the IRB’s Prisoner Representative for concurrence that the modification is “minor” and does not adversely affect the prisoners.
2. Continuing review of research that is otherwise eligible for expedited review (e.g., when all data collection is complete, etc.).
3. Prisoner research that involves ONLY obtaining *existing* data about prisoners may undergo “expedited” IRB review. Consultation with the Prisoner Representative will be obtained by the reviewer.

In all cases, the reviewer or Prisoner Representative, at their discretion, may elect to require review by the full-board.

Research involving prisoners is NOT eligible for exempt review, except for research involving a broader subject population that only incidentally includes prisoners.³

Special Criteria for Approval

In addition to the general criteria for IRB approval (e.g., risks are minimized and reasonable in relation to benefits, confidentiality measures are adequate, etc.), prisoner research must satisfy seven additional criteria related to ensuring special protections for prisoners (45 CFR 46.305(a)). These criteria include:

1. The research represents one of the categories of permissible research under 45 CFR 46.306(a)(2); those categories are:

³ Research that includes ANY prisoners and is subject to the Pre-2018 Common Rule is NOT eligible for exempt review. In general, the Pre-2018 Common Rule applies to research initially approved prior to January 21, 2019.

- i. 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;
 - ii. 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;
 - iii. 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 [federal] 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; or
 - iv. 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.
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 receiving such advantages in the limited-choice prison environment 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 subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides the IRB with written justification for following some other procedures, control subjects must be selected randomly from the group of available prisoners that meet the characteristics needed for that particular research proposal;
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.

To determine that all criteria are met, the IRB must be familiar with the specific conditions of the prison(s) or jail site(s) in which the research will be conducted.

*Minimal risk for prisoners is defined in 45 CFR 46.303(d) as: *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.* This definition differs from that for non-prisoners.

Special Requirements for Research with Juvenile Prisoners

Juvenile prisoners are especially vulnerable. Such research must address special protections necessary for both prisoners and children. For example, research with children typically requires parent/guardian consent and the assent of the child). In cases where juveniles are Wards of the State, different protections apply. State law may also affect research with incarcerated juveniles, and consultation from University Counsel may be needed. Researchers should contact the IRB office very early in the planning stages for guidance.

Special Certification Requirement for Federally-funded Research

For most federally funded research, ISU must certify (send documentation) to the Office of Human Research Protections (OHRP) that the ISU IRB reviewed the research and determined that it met all criteria for approval specified by federal regulations. Research may begin only after OHRP authorizes the research by notifying ISU that it agrees with the determinations of the ISU IRB. (Per 45 CFR 46.305(c) and 45 CFR 306(a)(1).

Guidance for Investigators Conducting Research with Prisoners

In general, IRB review of research involving prisoners proceeds just like IRB review of any research project. However, additional information is needed to ensure that all special protections are in place. To facilitate a smooth IRB review process, researchers should:

Provide sufficient information with the IRB application, including:

- Information about the specific prison or jail setting(s) in which the research will be conducted.
- Detailed plans for recruiting and obtaining the informed consent of prisoners in a manner that minimizes undue influence or coercion. Explaining the extent to which (and how) prison staff or authorities will be involved is critical.
- Any limitations on confidentiality should be described. For example, research activities in prisons are typically supervised by prison staff, meaning the prisoner's responses can be overheard. Additionally, responses from prisoners suggesting imminent threats of harm (to the prisoner or others) usually must be reported.
- Any unique requirements imposed by the prison or jail setting should be described. For example, the prison may have specific requirements for making initial contact with subjects. Informing the IRB of these requirements is helpful.
- A letter of cooperation or approval from the warden or head of each prison or jail site. The letter should include the following:

- Approval for the specific research project
- Assurance that prison officials will not request access to *individual responses or data* provided by the prisoners.
- Assurance that parole boards will not take into account the prisoners' participation in the research (or lack of participation) when making decisions about parole.
- Prisoners will not receive any special advantages or treatment for taking part in the research; nor will their choice to participate be a factor in any current or future disciplinary action.
- If prison staff will serve as research subjects, the warden should also confirm that participation (or lack thereof) will have no effect on the staff members' employment status or standing.

Be sure the informed consent process and document address the following:

- Information must be understandable to the subjects; consider reading level and any translation that may be needed.
- The voluntary nature of participation must be emphasized, and the consent process and document designed accordingly.
- Prisoners must be informed (usually in the consent document) that:
 - Their choice of whether or not to participate in the study will have no effect on parole decisions.
 - They will not receive any special advantages in the prison for participating.
 - Participation (or declining participation) will have no effect on any current or future disciplinary actions in the prison.
 - Confidentiality in the prison setting is limited, and any effects this may have (e.g., any requirements to report imminent threats of harm, that prison officials may overhear responses, etc.).
- When prison staff are research participants, they should be informed that their choice of whether or not to participate will have no effect on their employment status. Any employment-related risks or discomforts (e.g., due to confidentiality limitations, etc.) must be disclosed.

Consider seeking a federal Certificate of Confidentiality, if appropriate.

A [Certificate of Confidentiality](#) (CoC) protects against compelled disclosure (i.e., subpoena) of research data. Obtaining a CoC may be appropriate for studies that seek information from prisoners that could be used against them in legal proceedings (e.g., new disclosure of criminal activities, potential parole or probation violations, etc.).

Information about human subjects collected or used for projects supported by the National Institutes of Health (NIH) or the Centers for Disease Control (CDC) is automatically protected by a Certificate of Confidentiality. Researchers must inform participants of these protections and adhere to CoC disclosure restrictions.⁴

Plan ahead and allow plenty of time

Prison or jail facilities may each have their own policies, procedures, and preferences regarding the logistics of carrying out your research. In many cases, the logistics must be approved by the IRB (such as how you will recruit potential participants, the informed consent process, confidentiality and privacy provisions, etc.). Researchers are encouraged to work with the prison/jail sites to work out the logistics before seeking IRB approval.

Most federally funded prisoner research requires additional approval by the Office of Human Research Protections. This process can take time. Except in limited circumstances, prisoner research requires review by the convened IRB, including presence of the IRB's prisoner expert. The prisoner expert is generally available, but occasionally scheduling conflicts arise.

Document History

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⁴ For details see NIH Policy for Issuing Certificates of Confidentiality ([NOT-OD-17-109](#)) and [Certificates of Confidentiality for CDC Funded Research](#).