



RESEARCH INVOLVING PRISONERS

1. Overview

Federal regulations require additional protections for prisoners involved in research. These requirements include, among other things, that research involving prisoners (except for emergency use) may not be exempt from IRB review, the IRB reviewing prisoner research must include a prisoner or prisoner representative, and the proposed research must fall into one of the permissible categories described in the regulations.

The purpose of this policy is to describe the additional protections that must be provided to prisoners involved in research. These requirements apply to research involving prisoners and individuals who later become prisoners during the course of their research participation.

2. Definitions

Prisoner: An individual involuntarily confined or detained in a penal institution (e.g., prison, jail, or juvenile offender facility), with restricted ability to leave the 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 that provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

Minimal Risk: 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. *Note: The regulatory definition of “minimal risk” for research involving prisoners differs from the definition of minimal risk for research involving participants who are not prisoners.*

3. General Information

A. Prisoners may be convicted felons or as-yet untried individuals who are detained pending judicial action, as defined above.

The following are examples of individuals who are considered prisoners under the regulations:

- Individuals who are detained in a residential facility for court-ordered substance abuse treatment as a form of sentencing or as an 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 who are detained in a treatment center as a condition of parole

The following are examples of individuals who are NOT considered prisoners under the regulations:

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



- 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
 - Persons living in the community and sentenced to community-supervised monitoring, including parolees
 - Probationers and individuals wearing monitoring devices are generally not considered to be prisoners; however, the specific circumstances of the planned participant population should be carefully considered
- B.** Investigators are “engaged” in research involving prisoners when (for purposes of the research) they obtain data through intervention or interaction or identifiable private information about the prisoners. The following are examples of activities that constitute engagement in research involving prisoners:
- Seeking the informed consent of prisoners for research participation
 - Using or studying identifiable private information about prisoners for research purposes
 - Using or analyzing identifiable specimens obtained from prisoners for research purposes
 - Surveying prisoners for a research study
- C.** In addition to the “standard” regulatory requirements for IRB composition, when reviewing research involving prisoners the following requirements also apply:
- At least one member of the IRB must be a prisoner, or a prisoner representative with appropriate background and experience to serve in this capacity.
 - The prisoner representative should have a close working knowledge and understanding of prison conditions from the prisoner's perspective.
 - The prisoner representative should have the ability to express views independent of the prison administration.
 - If the research is reviewed by more than one IRB, only one IRB must satisfy this requirement.
 - A majority of IRB members (other than the prisoner representative) has no association with the prison(s) involved
- Note: The IRB must meet these composition requirements for all types of review by the convened IRB, including initial review, continuing review, and review of amendments.*
- D.** Expedited review of research involving prisoners must include a prisoner representative who meets the requirements to perform expedited review described in HRPP policy [\[Expedited and Administrative Review Procedures\]](#).
- E.** The DHHS exemption categories do not apply to research involving prisoners except when the exempt research examines a broader population that only incidentally involves prisoners.
- F.** Prisoners may be involved in the emergency use of an investigational drug or biologic or unapproved medical device (i.e., a category of exempt FDA research).



4. Permissible Categories of Research

A. The following are the categories of research that may involve prisoners:

1. Research on the possible causes, effects, and processes of incarceration and of criminal behavior, provided that the study presents no more than minimal risk for prisoners and no more than inconvenience to the participants
2. Research on prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk for prisoners and no more than inconvenience to the participants
3. 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 assault)

Note: Research in this category conducted or sponsored by DHHS may proceed only after the Secretary (DHHS) has consulted with appropriate experts, including experts in penology, medicine, and ethics and published notice in the Federal Register of his/her intent to approve the research.

4. Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or wellbeing of the participant

Note: For research conducted or sponsored by DHHS that require the assignment (in a manner consistent with protocols approved by the IRB) of prisoners to control groups that may not benefit from the research, the research may proceed only after the Secretary (DHHS) has consulted with appropriate experts, including experts in penology, medicine, and ethics and published notice in the Federal Register of his/her intent to approve the research.

B. Epidemiologic studies (e.g., related to chronic diseases, injuries, and environmental health) that do not meet the criteria above may also involve prisoners under all of the following conditions:

- The research presents no more than minimal risk for prisoners (e.g., interviews, collection of biological specimens, etc.) and no more than inconvenience to the prisoner-participants.
- Prisoners are not a particular focus of the research.
- The sole purpose of the research is either one of the following:
 - To describe the prevalence or incidence of a disease by identifying all cases
 - To study potential risk factor associations for a disease

5. Required IRB Findings

To approve research involving prisoners, along with determining that the regulatory criteria for approval are satisfied for non-prisoner participants, the IRB must make all of the following additional findings:

- The research represents one of the permissible categories ([described above](#)).
- Any possible advantages to the prisoner as a result of 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 such advantages in the “limited-choice” prison environment is impaired.

- The risks involved in the research are commensurate with risks that would be accepted by non-prisoner participants.
- Procedures for the selection of subjects within the prison are fair to all prisoners and free from arbitrary intervention by prison authorities or prisoners.
 - Unless the 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.
- The information is presented in language that is understandable to the participant population.
- 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/her parole.
- Where the IRB finds there may be a need for follow-up exams or care of subjects at the end of their participation, adequate provision has been made for this examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing subjects of this fact.

6. Documentation and Certification

- A. University IRBs that review prisoner research may be registered with OHRP by identifying the voting member(s) serving as a prisoner representative on the roster and stipulating that the prisoner representative will only count toward quorum when he/she is in attendance and reviewing research involving prisoners. Alternatively, a prisoner representative may be named as an alternate IRB member as described by HRPP policy [\[IRB Composition and IRB Member Roles and Responsibilities\]](#).
- B. Protocol-specific findings related to the additional protections required for research involving prisoners will be documented in the IRB meeting minutes (or IRB records for expedited review).
- C. For prisoner research conducted or supported by DHHS, certification that the IRB reviewed the research and made the findings required by the regulations must be provided to the Secretary (DHHS) through the Office for Human Research Protections (OHRP). Upon IRB approval, Office of Responsible Research Practices' staff will forward the certification request to OHRP. The following information should be included:
 - OHRP Federal-wide Assurance (FWA) number
 - IRB registration number
 - Date(s) of IRB review
 - Date of initial review and date of review for prisoner involvement, if not performed at the time of initial review
 - IRB-approved protocol
 - Any relevant grant application or proposal



- IRB application forms
 - Other information considered by the IRB during initial review
- D. Following its review of the certification request, if OHRP determines that the study involves one of the permissible categories of research, the institution will be notified by letter authorizing the involvement of prisoners in the proposed research. The research may proceed only after receipt of the OHRP authorization letter. If multiple institutions are engaged in the same prisoner research, each institution must request certification from OHRP unless an institution relied on the review of another IRB.
- E. Studies for which OHRP previously authorized prisoner involvement do not require “recertification” if amended unless the change to the research alters the applicability of the approved category of research.

7. When a Participant Becomes a Prisoner

- A. When an enrolled participant becomes a prisoner in a study that was not reviewed and approved by the IRB in accordance with the requirements for research involving prisoners [listed above](#):
- The principal investigator must notify the IRB as described by HRPP policy [[Event Reporting – Unanticipated Problems Involving Risks to Subjects or Others, Adverse Events, and Other Problems](#)].
 - All research activities with the now prisoner-participant must cease until the IRB can re-review the study (as applicable) to ensure that the requirements listed above have been satisfied.
 - If the participant is enrolled in a study that does not fall into one of the categories of permitted research, the participant cannot continue in the study.
 - In special circumstances in which the investigator asserts that it is in the best interests of the participant to remain in the study while incarcerated, the IRB chair may determine that the participant may continue to participate until the re-review requirements are completed.
- B. Upon receipt of notification that a previously enrolled research participant has become a prisoner and the investigator requests that the research is approved for prisoner participants, the IRB will promptly re-review the research in accordance with the review requirements. In these circumstances, some of the required findings may not be applicable (e.g., regarding the selection of participants within the prison if the participant was recruited outside of an incarcerated context). Any “non-applicable” findings should be documented along with the required findings.
- C. If an investigator anticipates that some of the participants in a proposed study population are likely to be prisoners or become prisoners during the course of the study, the IRB may review the research prospectively for prisoner involvement. In this case, some of the required findings may not apply. The IRB should use discretion in deciding whether sufficient information is available at the time of review to make the required findings or to wait until more specific information is available (e.g., the specific institution where participants will be prisoners may be needed to evaluate the local research context).



8. Applicable Regulations/Guidance

Pre-2018 and Final Rule (45 CFR 46.303, 45 CFR 46.305, 45 CFR 46.306), OHRP
“Guidance on the Involvement of Prisoners in Research” (05/23/03), OHRP Prisoner
Frequently Asked Questions (10/02/08)

9. History

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