

Guidance on Prisoner Research

The UNM IRB and the Office of Human Research Protections (OHRP) define **prisoner**, for the purpose of human research, as an individual involuntarily confined or detained in a penal institution, including persons:

- sentenced to such an institution under a criminal or civil statute;
- detained in other facilities (e.g. for the treatment of drug detoxification or alcoholism) by virtue of statutes or commitment procedures providing such alternatives to criminal prosecution or incarceration in a penal institution;
- detained, pending arraignment, trial, or sentencing (45 CFR 46.303(c)).

Individuals are prisoners if they are in any type of penal institution, such as 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. An adolescent detained in a juvenile detention facility is classified as a prisoner according to federal regulations.

Examples of the definition of prisoner:

- Individuals who are detained in a residential facility for court-ordered substance abuse treatment as a form of sentencing or alternative to incarceration; however, individuals who are receiving non-residential court-ordered substance abuse treatment and are residing in the community are not prisoners.
- Individuals with psychiatric illnesses who have been committed involuntarily to an institution as an alternative to a criminal prosecution or incarceration; however, 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, are not prisoners.
- 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, half-way house, including parolees, are not prisoners.
- Probationers and individuals wearing monitoring devices are generally not considered prisoners; however, situations of this kind frequently require an analysis of the particular circumstance of the planned participant population.

Examples of those NOT considered a prisoner:

- Parolees who are not detained but living in the community and sentenced to community-supervised monitoring, half-way house, including parolees, are not prisoners.
- Persons who are not “prisoners” when they enroll in the project, however are in jail for short periods of time at a later date if that short period of incarceration does not affect their participation in the project.

Background

Incarceration places prisoners under constraints that may affect their ability to make truly voluntary and autonomous decisions about whether or not to participate as participants in research. Prisoners, therefore,

constitute a vulnerable population for which additional protections are warranted. The IRB shall determine whether proposed studies with prisoners also satisfy the conditions under 45 CFR 46, Subpart C, “Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Participants.” These provisions of the federal regulations are intended to assure that 1) prisoners provide voluntary consent to participate in research; 2) prisoner’s confidentiality is rigorously protected; 3) and prisoners are not used as participants in studies for which non-incarcerated participants are suitable. These provisions apply whether the research involves individuals who are prisoners at the time of enrollment in the research or who become prisoners after they become enrolled in the research.

OHRP also requires that the IRB have among its members one or more individuals knowledgeable about and experienced in working with prisoners when research involving prisoners is to be reviewed. Additionally, a majority of the IRB, exclusive of the prisoner member(s), can have no association with the prison(s) involved apart from their membership on the IRB.

If research is conducted within the Bureau of Prisons, the research must comply with Department of Justice regulations [28 CFR 812.512](#). The UNM IRB will also consider applicable state laws in the review of these studies.

Categories of Research in Which Prisoners May Participate

To protect this project population, federal regulations stipulate that the only studies that may use prisoners are the following (46.306(a)(2)):

- Studies of the possible causes, effects, and processes of incarceration and criminal behavior, if those studies present no more than minimal risk or inconvenience to the participants.
- Studies of prisons as institutions, or of prisoners as incarcerated persons, if those studies present no more than minimal risk or inconvenience to the participants.
- Research on conditions affecting prisoners as a class (e.g., research on hepatitis, drug addiction, sexual assaults, and other conditions more prevalent in a prison population than elsewhere), but only after the secretary of the Department of Health and Human Services (DHHS) has consulted with experts in medicine, ethics, and penology and published a notice approving the proposed research in the Federal Register.
- Research on practices that are intended, and reasonably likely, to enhance the well-being of the participants; however, if some of the prisoners will be assigned to control groups which will not benefit from the research, then the project must first be approved by the secretary of DHHS after consultation with appropriate experts as described above.

The Secretary of DHHS waived the applicability of 45 CFR 46.305(a)(1) and 46.306(a)(2) for certain research conducted or supported by DHHS that involves epidemiologic studies that meet the following criteria:

- In which the sole purposes are to describe the prevalence or incidence of a disease by identifying all cases, or to project potential risk factor associations for a disease, and
- Where the institution responsible for the conduct of the research certifies to the OHRP, acting on behalf of the Secretary, that the IRB approved the research and fulfilled its duties under 45 CFR 46.305(a)(2)-(7) and determined and documented that the research presents no more than minimal

risk and no more than inconvenience to the prisoner-participants, and prisoners are not a particular focus of the research.

Prisoners are Targeted Participants or Anticipated Participants: Project Team Responsibilities

If the research population includes people who are greater possibility to be jailed during a project, and whose participation the PI would like to continue, the project should be reviewed as prisoner research. This would include studies intending to enroll parolees, street people, addicts, and prostitutes as these individuals are more likely to be arrested than the general population. Prisoners have the fundamental right to decide whether or not to participate in research.

The project team may not screen, recruit, or enroll any individual involuntarily confined or detained in a penal institution without written IRB approval. If the research is conducted or supported by DHHS, it also requires review and written approval by the Secretary (through OHRP) before any research activities may begin, including screening and enrollment.

Participants Incarcerated After Enrollment in Research Project: Project Team Responsibilities

If an enrolled participant becomes incarcerated (or otherwise meets the definition of prisoner as noted in this guidance), during the course of the project and the IRB has not previously reviewed the research proposal for prisoner populations, the researcher is responsible for providing written notification to the IRB within 5 days of knowledge of the incarceration.

All research interactions and interventions with, and obtaining identifiable private information about, the now-incarcerated prisoner-participant must cease. If the participant and the project team would like the participant to remain in the project, the project must be re-reviewed by the IRB under 45 CFR 46, Subpart C. No additional project procedures may take place until all requirements of subpart C have been satisfied with respect to the relevant protocol.

NOTE: OHRP has allowed one important exception. In special circumstances in which the principal researcher asserts that it is in the best interests of the participant to remain in the research project while incarcerated, the IRB Chair may determine that the participant may continue to participate in the research until the requirements of subpart C are satisfied.

In order to conduct any research with a participant 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 project.

If the prisoner will remain in the project the project team must submit an amendment request to the IRB using the correct forms and documents as described in the IRB Submission Checklist. Note that approval/permission from the correctional institution is one of the required documents.

The following must be included in the amendment request:

- Provisions for follow up examination of care following participation in the project, if applicable.

- A statement that the participant will not be presented with possible advantages to participation that would be greater in magnitude than the normal limited-choice environment of the prison. For example, you may state that the participant will not receive better living conditions, medical care, quality of food, amenities, or opportunities for earnings than what is normally provided in the prison environment.
- If participation in the project requires the participants to travel to a clinic, lab, or other project site outside of the prison, the consent form and protocol should state how transfer and transportation arrangements will be handled. **The researcher must consult with the correctional facility prior to drafting this language to ensure the facility can/will accommodate prisoner transport for the project.**
- A statement in the consent form that participation in the research will have no effect on sentencing, length of sentence or parole.

The Amendment Request form and all applicable documents must be submitted via IRBNet and received by the IRB within 10 business days of having knowledge of the incarceration.

Additional Duties of the IRB

- When the IRB reviews research that will involve prisoners they are required to first confirm that the proposed project fits within the permissible categories of research noted above. Then, it must determine: Any advantages that prisoners will realize as a result of participation in the research, when compared to general living conditions within the prison, are not so great as to impair the prisoner's ability to weigh the risks and benefits of participation and freely choose.
- The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers (usually demonstrated by enrolling non-prisoner participants from the community, as well).
- Procedures for selecting participants within the prison are fair, and free from arbitrary manipulation by prison authorities or other prisoners.
- Control participants will be selected randomly from among the group of eligible volunteers, unless the principal researcher justifies a different procedure.
- The information presented during recruitment and consent procedures is in a language, and level of complexity, understandable to the participant population.
- The IRB is assured that the parole board will not take research participation into account in making decisions about parole, and each prisoner is informed in advance that participation will have no effect on the possibility of parole.
- If medical follow-up is necessary to protect the health and welfare of the participants, adequate provision is made for such care, taking into account the varying length of prisoners' sentences.

Contact the IRB office at irbmaincampus@unm.edu or (505) 277-2644 with any questions about this guidance or working with prison populations.