Research Involving Prisoners

This document borrows from OHRP Prisoner Research FAQ's and provides background and guidance for those who would like to include prisoners in their research.

Prisoners are a vulnerable population under federal regulations and may not be enrolled in research without special considerations. The use of the term "vulnerable" in the context of human subjects protections does not refer to the susceptibility of harm, but rather, the inability or threat to voluntary consent to research. Thus, individuals involuntarily confined or detained are considered vulnerable because the constraints and contexts of incarceration or commitment may affect their decision-making process to participate or not. For example, some may think participating will help their justice processing outcomes; or, if they chose not to participate they could be further punished.

To address this voluntary consent issue, special procedures are in place in the Federal Regulations that provide additional safeguards for this special population, Subpart C of 45 CFR 46. For any research proposing to include prisoners as subjects, COMIRB ensures that the protocol adheres to these regulations.

Who is considered a prisoner?

A prisoner as defined by COMIRB policies and 45 CFR 46.303(c) is any individual involuntarily confined or detained in a penal institution or other institution under court order. 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.

Individuals are prisoners if they are unable to leave an institution voluntarily and/or being detained as a result of a court order. These institutions include any kind of jail, prison, or juvenile detention facility as well as a treatment facility for psychiatric illness or substance abuse problem, etc., under court order. Prisoners may also be untried persons who are detained pending judicial action, for example, arraignment or trial.

Specific examples include:

- Individuals detained in a residential treatment facility for court-ordered substance abuse treatment as a form of sentencing or alternative to incarceration are prisoners; however, those receiving treatment in a non-residential court-ordered program are not prisoners.
- Individuals with psychiatric illnesses who have been committed involuntarily as an alternative to criminal prosecution or incarceration are prisoners; however, individuals

who have voluntarily agreed to such treatment are not prisoners. Likewise, those who have been civilly committed to non-penal institutions because their illness makes them a danger to themselves or others, are not prisoners.

- Parolees who are detained in an inpatient treatment center as a condition of parole (release from incarceration) are prisoners; however, persons living in the community and sentenced to community-supervised monitoring are not prisoners.
- People under arrest but not yet charged are prisoners. Patients under police custody brought to an emergency room for medical care are prisoners. For example, if there is a police officer standing inside or outside the patient's room, if the patient's hand or foot is locked to the gurney, or if there is any other indication of police custody, the potential subjects are prisoners.
- Probationers and individuals wearing monitoring devices are generally not considered to be prisoners; however, situations like this depend on their context and require consideration of the particular circumstances of these individuals.

What are the regulatory considerations for prisoner research?

In summary, the major considerations are:

- The exemptions that generally apply to certain types of research do not apply to research involving prisoners, except for research aimed at involving a broader subject population that only incidentally includes prisoners (45 CFR 46.104(b)(2)).
- If the research is conducted or supported by DHHS, the University must certify to OHRP that COMIRB has reviewed the protocol and made all the required findings, and then receive OHRP authorization prior to research being initiated (45 CFR 46.305(c).
- In order to approve prisoner research, COMIRB must find that the proposed research falls into one of the permissible categories of research and make six other findings (cited below).
- COMIRB review must include a prisoner or prisoner representative (45 CFR 46.304(b) and if the study is reviewed by a full board, the convened meeting must also meet a membership requirement concerning the number of IRB members not associated with a prison/jail involved in the research (45 CFR 46.304(a).

What are the approval criteria for inclusion of prisoners in research?

As set forth in federal regulations at 45 CFR 46 Subpart C, COMIRB may approve research involving prisoners if it finds all of the criteria below are met.

1. Any possible advantages that the prisoner would gain through participation in the research, when compared to the general living conditions, medical care, quality of food, amenities, and opportunity for earnings in prison, is not of such a magnitude that the prisoner's ability to weigh the risks and benefits of the research in this limited-choice environment is impaired.

2. The risks involved in the research are commensurate with risks that would be accepted by non-prison participants.
3. Selection procedures within the prison are fair to all prisoners and immune from arbitrary intervention by prison authority or other prisoners. Control subjects must be selected randomly from the group of eligible prisoners for the research project unless the researcher provides COMIRB with justification in writing for a different procedure.
4. Any information given to subjects is presented in language that is understandable to them.
5. COMIRB is provided with adequate assurance that parole board(s) will not take into account a prisoner's participation in the research when making decisions regarding parole, and each prisoner is clearly informed in advance (*e.g.*, in the consent form) that participation will have no effect on their parole.
6. When there is a need for follow-up examination or care of subjects after the end of their participation in the research, adequate provision is made for such examination or care, taking into account the varying lengths of prisoner sentences. The research must fit into one or more of the five permissible categories described below.

Are there restrictions on the kind of research that include prisoners?

Yes. Protocols seeking to enroll prisoners must fall into one of the following federal categories:

Categories 1 and 2 – Research in these two categories is permissible only if the study presents no more than minimal risk and no more than inconvenience to the subjects. Minimal risk for prisoners is defined 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."

1. *The study of the possible causes, effects, and processes of incarceration, and of criminal behavior.*

   Examples of such research include substance use and mental health and its association with criminal activity, and research of familial illegal behavior and its effect on youth who happen to be in a detention facility.

2. *The study of prisons as institutional structures or of prisoners as incarcerated persons.*

   Examples of such research include an assessment and comparison of the medical units within prisons vs. jails, and the different roles that prisoners may play within the prison structure and how these roles may affect their quality of life.

Category 3 may proceed only after the Secretary of DHHS has consulted with appropriate experts in penology, medicine, and ethics, and has published notice in the Federal Register of their intent to approve the research.

3. *The study of conditions particularly affecting prisoners as a class.*

   Examples of such research include 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/or social or psychological pathology.

Category 4 is concerned with the study of practices that may improve the health or well-being of the subject. There are special requirements if a Category 4 study includes a control group.

4. *The study of practices, either innovative or accepted, which have the intent and reasonable probability of improving the health or well-being of the subject.*

   In this category, if the COMIRB-approved protocol is a study in which some prisoners will be assigned to a control group and these prisoners may not benefit from their participation in research, such research may proceed only after the Secretary of DHHS has consulted with appropriate experts, including experts in penology, medicine, and ethics, and has published notice in the Federal Register of their intent to approve the research. Control groups which may not benefit from the research include a control group receiving standard of care that the prisoners would otherwise receive, services as usual, or a placebo. An example is a behavioral health intervention trial for prisoners in which the intervention group receives group therapy while another group (the control) does not.

Category 5 concerns epidemiology studies.

5. *The DHHS Secretarial Waiver permits certain epidemiological research conducted or supported by DHHS functions.*

   Eligible epidemiological must satisfy the following criteria:

   - The sole purposes of the research are:
     - to describe the prevalence or incidence of a disease by identifying all cases, or
     - to study potential risk factor associations for a disease.
   - The research presents no more than minimal risk and no more than inconvenience to the prisoner-subjects, and
   - Prisoners are not a particular focus of the research.

   As described in the Federal Register:

   > The range of studies to which the proposed waiver would apply includes epidemiological research related to chronic diseases, injuries, and environmental health. This type of research uses epidemiologic methods

(such as interviews and collection of biologic specimens) that generally entail no more than minimal risk to the subjects.

An example of an epidemiological study that could be permitted under the proposed waiver is one in which all persons with HIV, but with none of the known risk factors for HIV, are asked to participate in a study involving an interview, review of medical records, and collection of a blood specimen. The purpose of the study is to determine other 5 potential risk factors for HIV. All states with mandatory HIV reporting laws report these cases to the Centers for Disease Control and Prevention (CDC), DHHS. Each person who meets the study definition would be asked to participate, and prisoners could well be members of the potential study group. In order for the study to be approved under this waiver, the IRB would need to ensure that, among other things, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of the data.

When COMIRB has approved the research and fulfilled its duties under 45 CFR 46.305(a)(2)-(7), COMIRB certifies to OHRP that an appropriately constituted committee has reviewed the protocol and found that it meets the criteria for approval of research involving prisoners.

Are there any specific requirements for inclusion of prisoners in research for the State of Colorado?

There are no specific Colorado statutes that address the inclusion of prisoners in state or local facilities in research.

How do I include prisoners held by the Colorado Department of Corrections?

The Colorado Department of Corrections (CDOC) by regulation permits and supports external research conducted by other state agencies, university students and professors, and other organizations interested in criminal justice issues. However, medical, pharmaceutical, and cosmetic experimentation are not permitted. Research and evaluation of correctional programs, services, and operations are allowed as described in Administrative Regulation (AR)1400-03 (https://drive.google.com/file/d/1lZoyygDvqVpljUYNhQEa7u1IzpqlwYuo/view).

Interested researchers should read this AR and submit the required Attachment A to the CDOC's Office of Planning and Analysis for consideration of their proposal/protocol. Administrative regulations are available on the CDOC policy page (http://www.colorado.gov/pacific/cdoc/policies-1).

The CDOC Attachment A requests a copy of the IRB application, approval letter and, if applicable, consent form. Their instructions indicate that these proposals to the CDOC can wait or not for department approval prior to obtaining IRB approval. However, the research may not begin before both CDOC and COMIRB approvals are obtained. If there are any problems about

whether CDOC or COMIRB approval needs to come first, researchers should contact COMIRB to discuss the situation.

The CDOC's Research Advisory Panel meets on the last Friday of each month to review requests to conduct research and makes recommendations regarding project approval. Each project must be approved by the research director, administrative head(s), and executive director. Requests must be submitted at least two weeks prior to the review date. Due to the multi-level review process, decisions may take several weeks, thus one must consider the length of time a review may take. Requests for expedited reviews are not considered.

If you are planning research in other states' penal institutions, you must follow its state laws and/or policies and procedures for research with prisoners.

What about research conducted in the Federal Bureau of Prisons?

The Federal Bureau of Prisons has adopted extensive regulations for researchers seeking to use federal prisoners as research subjects, 28 CFR 512 and Program Statement 1075.01. These regulations describe requirements for the research and researchers, and outline the responsibilities for Bureau staff in processing and monitoring the research. We advise researchers to review these regulations in advance. These regulations apply to all human subjects research even if the research is otherwise exempt under the Common Rule. The specific requirements for the research and the researchers are listed in 28 CFR 512.11 and include, but are not limited to, the following:

- The project must have an adequate research design and contribute to the advancement of knowledge about corrections.
- The project must not involve medical experimentation, cosmetic research, or pharmaceutical testing.
- Incentives may not be offered to help persuade inmate subjects to participate. However, soft drinks and snacks to be consumed at the test setting may be offered.
- The researcher must have academic preparation or experience in the area of study of the proposed research.
- The researcher must assume responsibility for actions of any person engaged to participate in the research project as an associate, assistant, or subcontractor to the researcher.
- The research design must be compatible with both the operation of prison facilities and protection of human subjects. The researcher must observe the rules of the institution or office in which the research is conducted.
- Any researcher who is a non-employee of the Bureau must sign a statement in which the researcher agrees to adhere to the provisions of 28 CFR 512.
- All research proposals will be reviewed by the Bureau Research Review Board.

- Except for computerized data records maintained at an official Department of Justice site, records which contain nondisclosable information directly traceable to a specific person may not be stored in, or introduced into, an electronic retrieval system.

If you are interested in doing research within the federal system, the Bureau of Prisons (BOP) has an application process that can be accessed at: https://www.bop.gov/resources/research_and_reports.jsp. The research may require IRB approval before it can be approved by the BOP. The BOP approval process typically takes 12 weeks for an expedited review research proposal.

What is needed to do research in ICE Facilities?

ICE detainees are a very vulnerable population. If you want to include these prisoners in your research, request ICE administrative approval prior to submitting a protocol to COMIRB. You may also discuss your proposal with a COMIRB Chair and staff prior to your submittal.

What about research under FDA regulations?

Current FDA regulations for the protection of human subjects do not include specific additional protections for research subjects who are prisoners, but the FDA does consider prisoners to be a vulnerable subject population. However, as noted above, CDOC and the Federal Bureau of Prisons prohibit the use of prisoners within federal facilities for medical experimentation, cosmetic research, or pharmaceutical testing.

How does the VA see prisoner research?

Research involving prisoners must not be conducted by VA investigators while on official duty, or at VA-approved off-site facilities unless a waiver has been granted by the Chief Research and Development Officer (CRADO). CRADO waivers may be issued after IRB approval and after a letter from the VA medical facility Director supporting the conduct of the VA study involving prisoners. Requirements for requesting a waiver may be obtained by contacting the VA ECHCS Research Office.

How do I access participants of the Colorado Division of Youth Services for research?

The Colorado Division of Youth Services (formerly the Colorado Division of Youth Corrections) is a division of the Colorado Department of Human Services and is based in Denver. The division supervises and cares for youth the district courts commit to its custody. It operates ten detention or residential facilities for youth aged 10 to 21. The division also manages juvenile parole in Colorado. To gain approval for recruiting and/or doing research in a CDYS population and/or site, you must contact the CDHS Research & Evaluation Unit at 303-866-7947 for instructions regarding their process for approval.

What do I do if a subject in my study becomes a prisoner?

If a human subject becomes a prisoner during the course of the study, and COMIRB did not approve the study to include prisoners, the investigator must promptly notify COMIRB by

submitting a UAP. All research interactions and interventions with the prisoner-subject must be suspended immediately, except as noted below. The collection of identifiable private information about the prisoner-subject must also cease. If the investigator wishes to have the prisoner-subject continue to participate in the research, COMIRB must promptly re-review the study for inclusion of prisoners. If the study is conducted or supported by DHHS, the University must also send a certification to OHRP and wait for a letter of authorization in reply. Otherwise, the prisoner subject must stop participating in the research, except as noted below.

OHRP allows one exception to these requirements. In special circumstances in which the investigator asserts that it is in the best interests of the subject to remain in the research study while incarcerated, the subject may continue to participate in the research until COMIRB approves the inclusion of prisoners and, if necessary, OHRP authorization is received. In this case, the investigator must promptly submit a study amendment so COMIRB can re-review the study.

What if I am enrolling a population at risk for arrest and/or detainment?

If you anticipate that some of the subjects might become prisoners (*i.e.*, be arrested) during the study, you may obtain COMIRB approval to allow these subjects to continue to participate in the study. Your protocol must still fall under one or more of the allowable categories of research.

What does COMIRB require for studies that include prisoners?

- Make sure your protocol falls under one or more of the permissible categories of research above.
- In the COMIRB application, indicate that you are enrolling prisoners and answer the additional questions in the section related to the inclusion of prisoners.
- If a facility has a research oversight approval process, please attach the approval letter and/or a description of the status. If there is no formal approval process, include a letter of support, indicating knowledge and understanding of the study, from the facility in which the research will take place.

What is the COMIRB reviewer looking for in a protocol?

COMIRB has prisoner research reviewers that have experience in this environment. In the Preliminary Studies section of the protocol, they will be looking for the researcher to show that they are experienced and knowledgeable about doing research with a prisoner population, the setting, or are working closely with a mentor with this experience and knowledge.

The protocol may need to describe routine research procedures in more detail than normal. In the protocol describe:

- Justification for the use of prisoners in the study. If applicable, delineate the protocol to be conducted in the jail, prison, detention center, or treatment facility from the overall project described in the general protocol.
- If and how detention facility staff are involved in conducting the research.
- How the recruitment and selection of prisoner participants will be done.
- How the project will obtain informed consent, and also state in the consent that "participation will not affect any sentencing, parole decisions or judicial outcomes."
- Customary treatment or services at these facilities for the condition being studied.
- Where research procedures will be done within the facility, who will be present (*e.g.*, correctional officer, etc.), how data will be collected, and how data will be protected.
- If applicable, has the facility approved the recording of interviews?
- If any materials will be given to the prisoner and if you are seeking institutional approval of distribution.
- What the incentive is, if applicable, and how it will be distributed. Most facilities will not allow direct payment.
- How the study will protect subject confidentiality from institutional staff and other prisoners.
- Plans for ensuring follow-up examination or care of participants after the end of their participation, if necessary.
- How risks specific to these settings are minimized.
- Whether a Certificate of Confidentiality will be obtained.
- State in the protocol that the prisoner participant will not be presented with possible advantages to participation that would be greater in magnitude than the normal limited-choice environment of the facility. For example, you may state that the subject will not receive better living conditions, medical care, and quality of food, amenities, or opportunities for earnings than what is normally provided in the prison environment. Thus, benefit for participation will be limited.
- If travel to a clinic, lab, or another study site outside of the facility is needed for the research. If so, the consent should state how transfer and transportation arrangements will be handled. Consult with the facility prior to submitting your protocol to COMIRB to ensure the facility can/will accommodate prisoner transport for the study and who will pay for it.

Detention facilities are tightly controlled. Routine research protocols and procedures need to be adjusted when using these settings. If you are not experienced in this area, you will need to involve faculty who are, or work with a co-PI mentor that is.

Research at Denver Health

The Correctional Care Medical Facility at Denver Health provides inpatient and outpatient care to patients from detentions and correctional jurisdictions. Denver Health provides care for inpatient clients through a guarded and locked unit within the hospital. They are also the contracted medical provider to the Denver City Downtown Detention Center and Denver

County Jail, with the provision of on-site medical, nursing, behavioral health, and dental services. As a contract provider, prisoner medical records are kept within the Denver Health medical record system. Thus, when planning research with Denver Health medical records, one must decide if prisoners will be part of the inclusion or exclusion criteria. If at any time you are collecting information or variables that would identify a person as a prisoner (for example, location within the hospital, who is billed for a service, context information in notes, how the patient entered the hospital, how they are currently monitored, etc.) you are enrolling prisoners.

Research at the Colorado Mental Health Institute at Pueblo

The Colorado Mental Health Institute at Pueblo is a forensic hospital that serves individuals with pending criminal charges who require evaluations of competency, individuals who have been found by a court to be incompetent to proceed (restoration treatment) and individuals found to be not guilty by reason of insanity. These patients meet the definition of a prisoner. Any research involving patients at this facility must fall under one of the permissible categories for prisoner research.

Contact COMIRB

Prisoner research may seem daunting to attempt, but it can be done, and scholarly research is encouraged. When thinking of doing this type of inquiry, we encourage you to contact COMIRB and ask to speak to a prisoner representative with any questions or advice prior to submitting a protocol. This action could greatly refine the protocol for this setting and facilitate the review process.