FAQS FOR ENROLLING PRISONERS ON RESEARCH OVERSEEN BY THE NIH IRB

Prisoners are a special population protected in the federal regulations 45 CFR 46 Subpart C.

1. What is a "prisoner"?

"Prisoner" is defined in the federal regulations 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)).

This means 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. However, as noted in the regulatory definition above, the term "prisoner" also goes beyond those being held in a traditional jail or prison and includes, for example, individuals with mental illness who are committed involuntarily to a psychiatric facility as an alternative to prosecution or incarceration.

The OHRP *Prisoner Research FAQs* provide the following helpful examples:

- Individuals who are detained in a residential facility for court-ordered substance abuse treatment as a form of sentencing or alternative to incarceration are prisoners; 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 are prisoners; however, individuals who have been voluntarily admitted to an institution for treatment of a psychiatric illness, or who have been civilly committed to nonpenal 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, including parolees, are not prisoners.
- Probationers and individuals wearing monitoring devices are generally not considered to be prisoners; however, situations of this kind frequently require an analysis of the particular circumstances of the planned subject population. Institutions may consult with OHRP when questions arise about research involving these populations.

2. As an investigator, what regulatory considerations should I know about if I want to enroll prisoners on my study?

Research conducted or supported by the Department of Health and Human Services (HHS) is

subject to the relevant HHS regulations for protection of human research subjects. This means that research conducted by NIH as an agency within HHS must comply with these federal regulations as well as the requirements of the subparts. In addition to requirements at Subpart A, Subpart C of these regulations specifically addresses the requirements when conducting human subjects research with prisoners. Details of the regulatory requirements that relate to enrolling prisoners are addressed below.

3. Why are there specific federal regulations about participation of prisoners in human subjects research?

Prior to the 1970s, there were many examples of abuse, exploitation, coercion, conflict of interest, lack of informed consent and other unethical practices that occurred during research conducted with prisoners. (See Bonham and Moreno (2008) and Christopher, Gorey and Rich (2022) as listed in the References for discussion of such research.) In 1976, the National Commission for the Protections of Biomedical and Behavioral Research released its review of the ethical issues surrounding inclusion of prisoners in research in its *Report and Recommendations: Research Involving Prisoners*. In this report, the National Commission took the position that "prisoners are, as a consequence of being prisoners, more subject to coerced choice and more readily available for the imposition of burdens that others will not willingly bear," and that they should "be protected against those forces that appear to compel their choices." Their view was that "the appropriate expression of respect [for persons] consists in protection from exploitation." This belief formed the basis for the current regulations involving prisoner research as codified in Subpart C of the federal regulation for protection of research subjects.

4. What research with prisoners can I conduct under the applicable federal regulations?

- Biomedical or behavioral research conducted or supported by Department of Health and Human Services (HHS) may involve prisoners as subjects only if:

  (1) The institution responsible for the conduct of the research has certified to the Secretary of HHS ("the Secretary") that the IRB has approved the research under § 46.305 of this subpart (which describes the duties of the IRB in such research as described in question 8); and

  (2) In the judgment of the Secretary the proposed research involves solely the following:

  (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;

  - This category could include study of conditions related to incarceration that pose no greater than minimal risk such as HIV/hepatitis status, mental illness or substance abuse and, for example, might also include sociobehavioral research or secondary research.

  (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:

- Studies in this category may proceed only after the Secretary has consulted with appropriate experts including experts in penology [*penology means the study of punishment of crime/treatment of the offender*], medicine and ethics and published a notice in the Federal Register (FR) of the intent to approve such research.
- This category can include research that is greater than minimal risk and does not require that there be prospect of direct benefit.
- Examples provided in the regulations include vaccine trials and 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.

(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 such studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups (e.g., placebo control) 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 FR, of his intent to approve such research.

- 2003 Epidemiologic Waiver allows HHS Epidemiology Research that does not fit into the existing categories (68 Fed. Reg. 36929 (Jun. 20, 2003)).

(1) This applies to epidemiology research if the sole purpose of the research is:

- To describe the prevalence/incidence of a disease by identifying all cases, or
- To study potential risk factor associations for a disease.

(2) In this case, the IRB certifies to OHRP that it has applied the relevant regulatory conditions (45 CFR 46.305(a)(2)-(7)), and the IRB must determine and document that:

- There is no more than minimal risk and no more than inconvenience to the prisoner-subjects, and
- Prisoners are not a focus of the research.

(3) Examples of research allowed under this category could include disease monitoring systems, health registries and various other epidemiological studies.

- Human subjects research that is exempt from IRB review only as follows:

(1) Exempt research involving prisoners is not allowed in research approved under the pre-2018 Common Rule.

(2) Under the (revised) 2018 Common Rule, research that otherwise meets the requirement as exempt may **only** be conducted with prisoners if it is aimed at

involving a broader subject population that only incidentally includes prisoners. Examples of exempt research that only incidentally includes prisoners include:

- Exempt secondary research use of information or biospecimens from subjects who are prisoners if that analysis is not seeking to examine prisoners as a population and only incidentally includes prisoners in the broader study.
- An exempt study that recruits subjects from a local community center to participate in a comparison of HIV educational materials even if some of the subjects became prisoners after enrollment.

- Prisoners cannot be involved in emergency research where the requirement for informed consent has been waived by the Secretary under the authority of 45 CFR 46.101(i).

5. What does "minimal risk" mean when doing research with prisoners?

The definition of minimal risk is different than the one used in Subparts A, B, and D. The definition as it relates to prisoners (45 CFR 46.303(d)) is:

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 that this definition:

- Refers to "physical or psychological" harm as opposed to "harm" or "discomfort."
- Uses the "healthy" person standard. At NIH, "*healthy persons*" is interpreted to mean healthy persons who are not incarcerated.

6. What are my responsibilities as PI when I anticipate enrollment and participation of prisoners on my research protocol?

- Investigators should be mindful of applicable state or local law, as well as Tribal law. Each state has a Department of Corrections (DOC) with specific regulations/rules, and links to specific state DOC sites can be found on the usa.gov website that provides information about corrections departments by state.
- Determine that you are allowed to collect data from the incarcerated person in that institution/state.
    a. You will likely need to fill out paperwork in the jurisdiction and/or state where the study is taking place.
    b. If you only want to enroll one individual at a specific prison, it is possible they will allow you to do this with institutional permission.
    c. Once determined, provide this documentation of permission from the institution/ DOC when you submit the protocol to the IRB.
- **Protocol considerations**: If you are only enrolling a few people who may be prisoners, and prisoners are not your targeted population, add a subsection in your protocol addressing this specific population of subjects. Broadly detail the ways in which data

collection would or would not change based on the person being incarcerated. You should first reach out to the relevant penal institution(s) to gain an understanding of the institution/jurisdiction, and what that institution/jurisdiction will allow.

- You then need to decide if you will go into the facility to collect *all* data. This should be stated in your protocol along with how you will ensure privacy and the ability of the participant to communicate with the team if needed. For example, will you provide them prepaid and pre-addressed envelopes or provide them with money on their phone account in order to be able to call and report an adverse event?
- This is not about merely ensuring privacy. You may not be able to do certain activities with people who are incarcerated unless the institution permits it, or unless it is so noninvasive that it makes institutional permission unnecessary for contact (e.g., mail correspondence). However, even correspondence can be read by DOC officials, meaning that privacy of the incarcerated subject cannot be guaranteed.
- If any data collection must be done outside the facility, how do you propose to transport the incarcerated subject or what data will you simply not collect? It is unlikely that a DOC will use its resources to transport an inmate for non-essential travel (non-emergency or not mandated travel), and they will not allow a study team to transport a prisoner. Prisoners are usually transported in shackles and kept under guard even for medical procedures outside of the facility.

- **Consent considerations:**
  - Consider how you will obtain consent and describe that process in the protocol. Even in the case where you simply want to ask questions as a scheduled visitor at the facility and will not collect samples (possibly helping get around larger institutional permissions), this will still be tricky and there are several ways to accomplish this. This interaction will not be like a typical informed consent process unless you have full institutional permission to interact with the incarcerated person in a research-specific way that would go well beyond what a typical visitor could do.
  - Create a new consent form for incarcerated potential subjects which adds to each existing section, where appropriate, language that is appropriate for this population based on what you have in the protocol. Your consent form must also describe any special conditions related to follow-up and how follow-up will occur. This should also be described in the protocol. The following should be included in addition to generic consent language:
    - "Your legal standing, including your sentence or any term of probation or parole will not be impacted by your decision to take part in this study or to refuse to volunteer for this study." When enrolling prisoners, this language about parole is required in the consent form in order for the IRB to approve it.

- "No data collected will be shared with the Department of Corrections."… etc.

7. Can the IRB waive or alter informed consent if the research involves prisoners?

If the IRB makes the appropriate findings regarding the waiver or alteration of informed consent requirements as required in Subpart A (§ 46.116 (e)-(f), research involving prisoners may be approved with a waiver or alteration of informed consent. Note the following caveats below:

- *However*, if informed consent is waived or altered, Subpart C of 45 CFR 46 still requires that the prisoner-subjects be clearly informed in advance that participation in the research will have no effect on their parole if such notification is relevant.
- In cases of emergency research where the requirement for informed consent has been waived by the Secretary of HHS under the authority of 45 CFR 46.101(i), prisoners cannot be enrolled.

8. What does the IRB need to do in order to approve a protocol that anticipates enrollment of prisoners?

- When the convened IRB reviews a protocol that includes a plan to enroll prisoners as subjects:
    - At least one member of the board must include a prisoner, or a prisoner representative with appropriate background and experience that provides a close working knowledge, understanding and appreciation of prison conditions from the perspective of the prisoner.
    - Except for the IRB member who is the prisoner/prisoner representative as required above, a majority of the Board cannot have any association with the prison(s) involved, apart from their membership on the Board.
- In order to approve research that involves prisoners, the IRB must find that, in addition to the requirements of Subpart A, the following seven conditions are met and must document the justification for each finding:
    1. The IRB must find that research falls into one of the categories noted in question four above.
    2. Any possible advantages accrued to the prisoner through participation, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not so great that they impair prisoners' ability to weigh risks of the research against the value of such advantages in the limited choice environment of the prison.
    3. Risks are same as those would be accepted by non-prisoner volunteers.
    4. Procedures for selection of subjects is fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the PI provides the IRB with written justification for following some other procedures, control subjects

must be randomly selected from the group of available prisoners who meet the characteristics needed for the protocol.

5. The information is presented in language which is understandable to prisoners.
6. Adequate assurance exists that parole boards will not take into consideration the prisoner's participation in the research in making decisions regarding parole. The informed consent document must clearly state that participation in the research will not impact parole. If the IRB has waived informed consent, the prisoners must still be informed that participation in the research will not impact parole as is explained in question 7 above.
7. For studies where post-study follow up care will be needed, there must be adequate provision for this follow up that takes into account the varying length of individual prisoners' sentences and for informing the prisoners of this fact in the informed consent document.

9. What comes next if the IRB approves my research?

The NIH IRB must send a Certification Form to OHRP for all protocols that it oversees that involve prisoners including studies that fall under the Epidemiologic Waiver. The Certification Form will include the following:

- The research proposal (i.e., IRB approved protocol, IRB application forms, and information requested by the IRB at Initial Review);
- The risk category determined by the IRB along with the IRB 's justification for the category selected; and
- If the research is approved under the Epidemiologic Waiver, the Certification Form will include the IRB's determination and justification regarding:
    - minimal risk/inconvenience, and
    - prisoners are not the focus of the research.

Note that the research <u>cannot</u> be initiated until OHRP issues its approval.

10. What are my responsibilities as an investigator when a subject becomes a prisoner after enrollment on my research protocol when the protocol was not previously reviewed and approved by the IRB for prisoner participation?

- If a subject becomes incarcerated and the IRB and OHRP have not previously approved prisoner participation on your research protocol, you must notify IRBO as soon as possible using the relevant event/reportable new information form in the NIH eIRB system.
- All research interactions, interventions with, and obtaining identifiable private information about the now-incarcerated prisoner-subject, must be halted until IRB and OHRP approval is obtained.
- If it is in the best interest of the subject to remain on study while incarcerated, you must promptly notify IRBO and obtain permission from the IRB Chair to continue activities needed to

ensure the safety and welfare of the now prisoner-subject until IRB and OHRP approval is obtained.

  - Submit an amendment in the NIH electronic IRB system for review by the convened IRB requesting permission for the prisoner-subject to remain on study and include any additional safeguards and changes to procedures (if any) needed for the now-prisoner-subject to remain on the research.

- No research activities involving the prisoner-subject may take place prior to IRB approval and receipt of a letter of authorization from OHRP, except for those necessary for the welfare or safety of the prisoner-subject.
- If the IRB disapproves continued participation of the prisoner-subject, the subject must be taken off study.
- A subject may move into and out of "prisoner" status without requiring IRB review under Subpart C *so long as* ***no research interactions occur while the subject is considered a prisoner***. You still must notify the IRB as soon as possible using the relevant event/reportable new information form in the eIRB system. For example, if a subject on a natural history study becomes incarcerated on a minor drug charge resulting only in a short jail sentence, and no research activities occur during their incarceration, they may resume study participation when they are no longer considered a prisoner. In such a case, review under the Subpart C regulations is not required.
- If you are not sure whether Subpart C would apply in a given situation, please consult IRBO immediately.

11. Where can I find more information about conducting human subjects research with prisoners?

68 Fed. Reg. 36929 (Jun. 20, 2003) - *Waiver of the Applicability of Certain Provisions of DHHS Regulations for Protection of Human Research Subjects for Department of Health and Human Services Conducted or Supported Epidemiologic Research Involving Prisoners as Subjects*

45 CFR 46, Subpart C: *Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects*

Bonham VH, Moreno JD. Research with Captive Populations: Prisoners, Students and Soldiers. In *The Oxford Textbook of Clinical Research Ethics,* EJ Emmanuel, C Grady, RA Crouch, RK Lie, FG Miller, and D Wendler (Eds), (2008), Oxford University Press, NY, NY.

Christopher PP, Gorey JG, Rich, J. Subpart C Research: Additional Protections for Prisoners. In *Institutional Review Board Management and Function*, EA Bankert, BG Gordon, EA Hurley and SP Shriver (Eds), (2022), Jones and Bartlett Learning, Burlington, MA.

NIH HRPP Policy 401, *Research Involving Prisoners*

OHRP Prisoner Research FAQs

OHRP Guidance – Prisoner Involvement in Research (May 23, 2003)