GUIDELINE FOR ENROLLING PRISONERS AS PARTICIPANTS IN RESEARCH

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

If you are targeting prisoners as a population to enroll in your study or have a participant who becomes a prisoner while enrolled and you want to keep that person on the study, then these regulations apply to your protocol.

Start by reviewing the OHRP Prisoner Research FAQs and Policy 401.

What is a prisoner?

"Prisoner" means 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)).

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.

Note this exception: Individuals on probation or wearing monitoring devices are generally not considered to be prisoners.

What about state law?

You will need to know what the state law is for the state where you are enrolling prisoners, and how it is applicable to your research. Each state has a Department of Corrections (DOC) with specific regulations/rules that you must follow.

What is minimal risk for research with prisoners?

The definition of minimal risk is different than the one used in Subparts A, B, and D. The definition in 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.

What do I need to do first?

1. Determine that you are allowed to collect specimens and/or data from the incarcerated person(s) 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.

2. **Protocol considerations**: If you know that you will be targeting prisoners, or you have a participant already enrolled who has become a prisoner and you wish to keep this person on your study, add a subsection in your protocol addressing this specific vulnerable 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 penal institution(s) to gain an understanding of the institution/jurisdiction, and what that institution/jurisdiction will allow. If you will have incarcerated people at more than one penal institution, then the data collection section of the protocol should be broad enough to allow for variations in what different institutions may or may not allow.

    a. Having established that, you will 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 ensure 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?

    b. This is not about merely ensuring privacy, rather that you may not be able to do certain tasks with people who are incarcerated unless the institution permits it, or unless it is so noninvasive so as to make the institutional permission unnecessary for contact (e.g., mail correspondence). However, even correspondence can be read by DOC officials, meaning that privacy of the incarcerated person cannot be guaranteed.

    c. If any data collection absolutely has to be done outside the facility, then 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 either. Prisoners are usually transported shackled and are kept under guard even for medical procedures outside of the facility.

3. **Consent considerations:** You need to consider how you will obtain consent and describe that process in the protocol. Even in the case where you simply want to ask questions and go into the facility as a scheduled visitor to ask questions but collect no samples, this will still be tricky and there are several ways to do it, none of which will look like a typical informed consent process unless you have full institutional permissions to interact with the incarcerated person in research-specific way that would go well beyond what a typical visitor could do.

    You will also need to create a new consent for incarcerated people which adds to each existing section, where appropriate, language that is appropriate for this population based on what you put in the protocol. Your consent must also describe any special conditions of follow up and how follow up will occur, if applicable to your protocol. This should be included in addition to generic consent language, such as:

a. "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." This language about parole is required in order to be approvable by the IRB.

b. "No data collected will be shared with the Department of Corrections." (if you know this to be true) … etc.

What does the IRB need to do?

In order to approve research that involves prisoners, the IRB must find that the following seven conditions are met and document the justification for each finding:

1. 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 is impaired.
2. Risks are same as those would be accepted by non-prisoners.
3. Procedures for selection of subjects is fair to all prisoners and immune from intervention by prison authorities in prisons. Control subjects must be randomly selected from the group of available prisoners who meet the characteristics needed for the protocol.
4. The information is presented in language which is understandable to prisoners.
5. 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.
6. For studies that need follow up, there must be adequate provision for the examination and/or care required after the end of their participation, considering the varying length of individual sentences; and for informing the prisoners of this fact in the informed consent document.
7. The IRB must find that the research falls in one of the following categories and must document rationale for category selected:
    a) "Minimal risk" and "no more than inconvenience" to subjects AND is a study of causes, effects and process of incarceration and of criminal behavior
    b) "Minimal risk" and "no more than inconvenience" to subjects AND is a study of prisons as institutional structures or of prisoners as incarcerated persons
    c) 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 HHS Secretary has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the FEDERAL REGISTER, of his intent to approve such research; or

d) 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.

e) A waiver exists to allow HHS Epidemiology Research that does not fit into the first four categories. This applies to epidemiology research if the sole purpose of the research is:

- To describe the prevalence/incidence of a disease, or
- To study potential risk factor(s) for a disease.

If this applies, the IRB must determine and document:

- 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.

What comes next if the IRB approves my research?

As all research in the NIH IRP is funded by the federal government, the IRB must send a Certification Letter to OHRP for all HHS protocols involving prisoners including studies that fall under the waiver.

- Include the research proposal (i.e., IRB approved protocol, IRB application forms, and information requested by the IRB at Initial Review);
- Include the risk category selected and provide the IRB's justification for the category selected; and
- The Waiver for Epidemiology Research, if applicable: Provide the IRB's determination and justification regarding:
  - minimal risk/inconvenience, and
  - that the prisoner is not the focus of the research.

Note: For research funded by an agency/office of the Department of Health and Human Services (HHS), the NIH will certify to the Office for Human Research Protection (OHRP) that the IRB completed its review of permissible research and that the seven additional requirements are met. Research activities may not proceed until OHRP issues written approval of the study through published notice in the Federal Register and notice to the NIH.

Note: Per federal regulations 45 CFR 46.104(b)(2), research involving prisoners may not be deemed exempt.