Research Involving Prisoners

I. Statement

IRB review and approval of research designed to study incarcerated persons, or persons likely to become incarcerated, is a multistep process and must be conducted in accordance with the requirements in 45 CFR 46 Subparts A (Common Rule) and C (Additional Prisoner Considerations) prior to any interaction or intervention with prisoners or research participants who are now classified as prisoners, as well as data about prisoners.

According to 45 CFR 46.303(c):
"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. For more information on who may fall into this definition refers to OHRP FAQs.

A. The steps include:

1. Review of the research by an IRB that is constituted with at least one voting member of the Board in attendance who is a prisoner or prisoner representative;
    a. Subpart C includes a modified definition of "no more than 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.;
2. Determinations by the Board that the seven findings for research under 45 CFR 46.305(a) are fulfilled.
3. Federally sponsored studies: Once IRB review is complete and contingencies have been addressed, the UM Institutional Official submits completed Subpart C Certification Form regarding the completed IRB review, and awaits receipt of an authorization letter from OHRP with the judgment of the HHS Secretary that the research is permissible under 45 CFR 46.306(a).

4. Studies without federal funding: Once the IRB review is complete and contingencies have been addressed, the IRB will certify to the Institutional Official (IO) or Deputy Institutional Official (DIO) that the research meets the criteria for approval of research with prisoners. The IO or DIO assumes the role of the HHS Secretary. (*Reference*: HRPP Operations Manual Part 7.II.B)
5. Studies targeting prisoners must have facility and/or Department of Corrections approval before submitting for IRB approval, or at the minimum, a draft approval indicating that the facility is willing to consider the research.
6. Studies involving incidental inclusion of prisoners may receive conditional approval prior to Department of Corrections approval, in which case a follow-up submission is required once these approvals are in place.
7. If not known ahead of time, submit by ORIO an amendment when each facility's permission is received.
8. Wardens may choose to provide permission to conduct research at the facility over the course of the study, or for research activities with a specific subject.
9. If early study activities will not require prisoner interaction, the IRB may approve these activities and require an amendment, including a DOC letter, before any prisoner interaction takes place.

This process may be lengthy. Contact the IRBMED or IRB-HSBS office for assistance with the process.

II. Process

Research may include prisoners at different times throughout the course of a study. Research may target prisoners for the research, and research may include participants who become incarcerated during their participation. See below for instructions for different scenarios.

A. Prisoners at the time of enrollment

For those studies that target individuals who are incarcerated (i.e. the study will take place within the jail/prison) the protocol should detail how participants will be recruited and what role the jail/prison staff will have in the recruitment/data collection process. Participants should be informed of the following within the consent:

1. A statement informing participants that their participation or lack thereof will not impact their treatment at the facility nor any probation/parole.
2. A statement that privacy and confidentiality of their participation or their records can not be guaranteed due to the jail/prison rules/regulations. (e.g. staff will likely need to escort them to various locations for their participation, facility recording may be taking place in the room in which the data collection take place, their data may be viewed by prison staff)
3. The protocol should detail the reporting expectations to the IRB (for instance, whether the IRB will be informed of the number of current and former prisoners active in the study, when an ORIO will be submitted, etc.).

B. Participants may become incarcerated, where interaction/intervention during incarceration is expected

Participant populations in which the possibility of incarceration is expected should seek approval to conduct research with prisoners if the principal investigator would like to continue interacting with the now-incarcerated subject, including follow-up surveys. Other intervention may be difficult to continue after incarceration since protocols may require changes. This is very study-specific and should be clearly described in the protocol.

The IRB should be notified by ORIO when a subject becomes incarcerated, with documentation of the correctional facility approval uploaded. Note: it is not necessary to notify the IRB when a subject first becomes incarcerated but the appropriate correctional facility approval has not yet been obtained.

C. Participants may become incarcerated, and NO interaction/intervention will take place during incarceration

If a participant becomes incarcerated and if the study is not approved for research with prisoners, no study activity may occur with that subject until they are released. This includes follow-up surveys, contact with the subject, or further intervention.

Depending on the anticipated length of the incarceration, the participant might miss study-related interactions, and depending on the protocol, might need to be withdrawn from the study. The participant may resume study activities after incarceration, if appropriate. The principal investigator should assess data integrity and participant benefit/safety.

Refer to the table below to determine reporting requirements.

D. Participant becomes incarcerated in a study not approved for prisoners

If a study participant becomes incarcerated during the conduct of a study that is not approved for prisoner research, **and** participant intervention/interaction is expected to continue during the incarceration, **then** promptly submit an ORIO (Other Related Information or Occurrence).

Situation	ORIO subtype	Considerations
Research activities with this participant will continue during incarceration	Subject Incarceration	ALSO submit an Amendment for re-review according to Subpart C (see above).
Research activities with this participant will be paused, resulting in missed visits, procedures and/or data collection. Participant participation will resume after incarceration.	Subject Incarceration	Include whether any wash-out procedures are necessary, and how the study team will re-contact after incarceration
Participant will be withdrawn from the study	Subject Withdrawal	Include whether any wash-out procedures are necessary, and whether any follow-up information will be collected after withdrawal
No research activities with this participant are scheduled during the incarceration. Participation will resume after incarceration. There is no expectation that data collection or study procedures will be affected.	**No ORIO necessary**	

No ORIO is necessary if the study design is such that no study procedures would have taken place during the time of incarceration (e.g. the Participant is in long-term follow-up through medical record review only).

A "Subject Incarceration" ORIO is not necessary if the study team learns that a Participant was formerly incarcerated and already has been released. However, any missed visits, procedure, and/or data collection should be tracked as Protocol Violations (see ORIO guidance).

If the participant is now classified as a prisoner and will continue research participation during incarceration, the IRB must promptly re-review the research application in accordance with the requirements in 45 CFR 46 subpart C.

E. Points to remember

Note: If a study has been reviewed/approved under subpart C, these points would not apply.

1. **Do not** perform any study intervention or interaction (**except** those necessary to avoid *immediate* harm to the Participant, as determined by the PI) or collect any Protected Health Information (PHI). Study team may confirm incarceration by contacting the detention facility. If it is in *the best interests of the Participant* to remain in the research study while incarcerated, the PI should contact the IRB Chair on call, who may make the preliminary determination that the participant may continue to participate in the research until IRB re-reviews according to subpart C requirements.
2. Prepare and submit both of the following eResearch applications:
    a. **Amendment**
    In the Amendment Title include "Prisoner Research approval," "Participant now prisoner," or something similar.
    b. **ORIO**
    "Subject Incarceration" sub-type

For studies that may involve probationers or individuals with monitoring devices, and for any other situations where prisoner status may not be clear, refer to IRB FAQs. If questions remain, consult with IRB and then consult with the U-M Office of General Counsel (OGC).

III. Resources

A. University of Michigan HRPP Operations Manual
Part 7.II.B (Participant Protection)
Part 11.II.D.1 (State Laws, Additional Protections for Vulnerable Populations)
B. Michigan Department of Corrections
Policy Directive 01.04.120 "Research Involving Corrections Facilities or Offenders"
C. Office of Human Research Protections (OHRP)
Regulations: 45 CFR 46 Subpart C: Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects
D. FAQs Topic: Prisoner Research
E. Guidance Prisoner Involvement in Research (2003)
F. Guidance Prisoner Research Certification (2020)