

Tip Sheet 18: Review of Research involving Prisoners and the Role of the Prisoner Representative

Related Accreditation Elements: II.1.A., II.2.A., II.2.B., II.2.C., II.2.D., II.2.E., II.4.A., and II.4.B.

The DHHS regulations provide additional protections for research involving prisoners in Subpart C (Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoner as Subjects). These regulations apply to any research funded by the DHHS, and can be voluntarily applied to research that is not sponsored by the DHHS. For research involving prisoners that is not sponsored by DHHS, organizations can develop equivalent standards of protection in place of Subpart C. The FDA has no specific provisions for research involving prisoners but state that the IRB should be cognizant of the special problems of research involving vulnerable populations, including prisoners.

This Tip Sheet provides the procedural details that AAHRPP is looking for, in addition to the regulatory requirements, when organizations conduct research involving prisoners.

Recommended Content:

For research involving prisoners reviewed by the convened IRB:

1. The prisoner representative must be a voting member of the IRB.
 - a. The prisoner representative may be listed as an alternative member who becomes a voting member when needed.
2. The prisoner representative must review research involving prisoners, focusing on the requirements in Subpart C or equivalent protections.
 - a. The prisoner representative must receive all review materials pertaining to the research (same as primary reviewer)
3. The prisoner representative must be present at a convened meeting when the research involving prisoners is reviewed. If the prisoner representative is not present, research involving prisoners cannot be reviewed or approved.
 - a. The prisoner representative may attend the meeting by phone, video-conference, or webinar, as long as the representative is able to participate in the meeting as if they were present in person at the meeting.
4. The prisoner representative must present his/her review either orally or in writing at the convened meeting of the IRB when the research involving prisoners is reviewed.
5. Minor modifications to research may be reviewed using the expedited procedure described below, using either of the two procedures described based on the type of modification.

6. Modifications involving more than a minor change reviewed by the convened IRB – must use the same procedures for initial review including the responsibility of the prisoner representative to review the modification and participate in the meeting (as described above).
7. Continuing review – must use the same procedures for initial review including the responsibility of the prisoner representative to review the continuing review materials and participate in the meeting (as described above).
 - a. If no participants have been enrolled, the research may receive continuing review using the expedited procedure under expedited category #8.

If your Organization reviews research involving prisoners by the expedited procedure, it may use the following two options:

For research involving interaction with prisoners reviewed by the expedited procedure:

1. Research involving interaction with prisoners may be reviewed by the expedited procedure, if a determination is made that the research involves no greater than minimal risk for the prison population being studied.
 - a. The prisoner representative must concur with the determination that the research involves no greater than minimal risk.
2. The prisoner representative must review the research as a reviewer, designated by the chair, or consultant. This may be as the sole reviewer or in addition to another reviewer, as appropriate.
3. Review of modifications and continuing review must use the same procedures for initial review using this expedited procedure including the responsibility of the prisoner representative.

For research that does not involve interaction with prisoners (e.g. existing data, record review) reviewed by the expedited procedure:

1. Research that does not involve interaction with prisoners may be reviewed by the expedited procedure, if a determination is made that the research involves no greater than minimal risk for the prison population being studied.
2. Review by a prisoner representative is not required.
3. The prisoner representative may review the research as a reviewer or consultant if designated by the IRB chair.
4. Review of modifications and continuing review must use the same procedures as initial review.

If your Organization grants exempt determinations for research involving prisoners, it may use the following option:

1. If Subpart C is applicable either by funding requirement or voluntarily (e.g. Subpart C box is checked on the federal wide assurance) research involving prisoners cannot be deemed exempt.
2. If Subpart C is not applicable, research using data, samples, or materials that involves prisoners or that may involve prisoners but qualifies for an exemption might be granted an exemption. It must be determined that an exemption is appropriate for the prison population being studied.
 - a. The prisoner representative may be consulted for exempt determinations involving prisoners but is not required.
 - b. An exemption may not be granted if the research involves interaction with prisoners (including obtaining consent).

If a participant becomes a prisoner while enrolled in a research study that was not reviewed according to Subpart C:

1. When Subpart C applies:
 - a. Confirm that the participant meets the definition of a prisoner.
 - b. Terminate enrollment or review the research study under Subpart C if it feasible for the participant to remain in the study.
 - c. Before terminating the enrollment of the incarcerated participant the IRB should consider the risks associated with terminating participation in the study.
 - d. If the participant cannot be terminated for health or safety reasons
 - i. Keep the participant enrolled in the study and review the research under Subpart C.
 - A. If some the requirements of Subpart C cannot be met, but it is in the best interests of the participant to remain in the study, keep the participant enrolled and inform OHRP of the decision along with the justification.
 - ii. Remove the participant from the study and keep the participant on the study intervention under an alternate mechanism such as compassionate use, off label use, etc.
2. When Subpart C does not apply and the IRB has written procedures for providing equivalent protections:
 - a. Confirm that the participant meets the definition of a prisoner.
 - b. Decide whether it is in the best interests of the participant to remain in the study or to terminate enrollment.
 - c. Also decide whether it is feasible for the participant to remain in the study.
 - d. If it is in the best interests of the participant to remain in the study, keep the participant in the study and review the research at next meeting of the convened IRB.
3. When IRBs do not have written procedures for research involving prisoners:

- a. Confirm that the participant meets the definition of a prisoner.
- b. Decide whether it is in the best interests of the participant to remain in the study or to terminate enrollment.
- c. Also decide whether it is feasible for the participant to remain in the study.
- d. Determine whether Subpart C applies.
 - i. If Subpart C applies:
 - A. Find an IRB that can review the study or refer to the federal regulations and identify a prisoner representative so that your IRB can review the study.
 - ii. If Subpart C does not apply:
 - A. Find an IRB that can review the study or develop written procedures for providing equivalent protections.

Note: If a participant is incarcerated temporarily while enrolled in a study:

1. If the temporary incarceration has no effect on the study, keep the participant enrolled.
2. If the temporary incarceration has an effect on the study, handle according to the above guidance.

Definitions:

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 (45CFR46.303(c)). If Subpart C does not apply the Organization may use an equivalent definition of prisoners.

Minimal risk for prisoners is defined by the regulations 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 (45 CFR 46.303(d)). Furthermore, the regulations state that the IRB must find that the risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers (45 CFR 46.305(a)(3)). If Subpart C does not apply the Organization may use an equivalent definition of minimal risk for prisoners.