

Special Categories of Research - Prisoners

Content Applies To

Mayo Clinic Human Research Protection Program

Purpose

This document describes the additional protections required when biomedical and/or behavioral research involves prisoners as research subjects.

Key Terms

Prisoner: Any individual involuntarily confined or detained in a penal institution. The term, *prisoner*, 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.

DHHS: Department of Health and Human Services.

Secretary: The Secretary of DHHS and any other officer or employee of DHHS to whom authority has been delegated.

OHRP: The Office for Human Research Protections is a department within DHHS which provides leadership for the protection of the rights, welfare, and well-being of subjects involved in research conducted or supported by DHHS.

IRB Review of Research

It is the policy of the Mayo Clinic Office for Human Research Protection - Institutional Review Board (IRB) to review human subject research involving prisoners and approve only research that satisfies the requirements of:

- 45 CFR 46, Subpart C, *Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects*, or
- Equivalent protections as allowed by law.

Requirements for reviews of research involving prisoners apply to initial review, continuing review, and review of modifications.

DHHS-Supported Research

When the IRB approves DHHS-supported research involving prisoners, the Mayo Clinic IRB prepares an OHRP Prisoner Certification Letter and sends it to the DHHS Secretary. The letter states that the IRB review has met the applicable requirements of 45 CFR 46 Subpart A and Subpart C, 45 CFR 46.305(a) and that the proposed research represents one of the permissible categories of research under 45 CFR 46.306(a) (2).

The IRB must receive OHRP authorization prior to allowing an investigator to initiate DHHS-supported research involving prisoners. See the section on the [Preparation of a Prisoner Certification Letter to OHRP](#) in this document for further details.

Investigator Responsibilities

1. The Investigator describes the target population for the research and provides justification for inclusion of prisoners in his/her IRB application submission.
2. If the proposed target population has increased potential to become prisoners, in anticipation of this occurrence, the Investigator may request that the IRB review the research project in accordance with this policy.
3. The Investigator obtains and provides documentation of approval from the detention or correctional facility involved (i.e., prisons, jails, workhouses, etc.) to the IRB.
4. The Investigator provides any additional documents or materials required for certification to OHRP if the research is DHHS-supported.
5. The Investigator does not screen, recruit, or enroll any individual involuntarily confined or detained in a penal institution without IRB approval and, for DHHS-supported research, the additional required OHRP prisoner certification.

Convened IRB Responsibilities

1. At least one member of the IRB reviewing research involving prisoners is a prisoner representative with appropriate background and experience to serve in that capacity.
2. 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.
3. The prisoner representative must review research involving prisoners, focusing on the requirements in Subpart C or equivalent protections.
 - a. The prisoner representative must have access to all review materials pertaining to the research.
4. The prisoner representative must be in attendance at the convened IRB meeting when the research involving prisoners is reviewed. If the prisoner representative is not in attendance, research involving prisoners cannot be reviewed.
 - a. The prisoner representative may attend the meeting with the aid of conferencing technology (e.g. phone, video or web conference), as long as the representative is able to participate in the meeting as if they were attending in person.
5. The prisoner representative must present his/her review either orally or in writing during the convened IRB meeting when the research involving prisoners is reviewed.
6. Excluding the prisoner representative, a majority of the reviewing IRB members have no association with the prison(s) involved, apart from membership on the IRB.

7. Minor modifications to research may be reviewed using the expedited procedure.
8. Modifications and continuing review reports reviewed by the convened IRB must use the same procedures as for initial review including the responsibility of the prisoner representative to review the modification and participate in the meeting (as described above).
9. If a particular research project is to be reviewed by more than one convened IRB, only one IRB need satisfy these requirements.

Documentation of IRB Review

When applying the additional protections at 45 CFR 46 Subpart C the regulatory determinations and related protocol-specific findings relating to the seven additional duties of the IRB under 45 CFR 46.305(a) And the permitted category of HHS-supported research involving prisoners per 45 CFR 46.306(a) (2) are documented in the IRB minutes.

Expedited Review of Research Involving Interaction with Prisoners

Research that involves interaction with prisoners is forwarded by IRB staff for review during a convened IRB meeting with a prisoner representative in attendance.

Exemptions

Exemptions that generally apply to certain types of research involving human subjects do not apply to research involving prisoners (45 CFR 46.101, footnote 1).

Emergency Research Consent Waiver

Waiver of informed consent in certain emergency research is not applicable to research involving prisoners (61 FR 51531, October 2, 1996).

Epidemiological Research Waiver

The requirement that the research involving prisoners falls into one of the 4 categories under 45 CFR 46.306 may be waived if the research involving prisoners has as its sole purpose of (i) describing the prevalence or incidence of a disease by identifying all cases, or (ii) studying potential risk factor associations for a disease.

The IRB must review the research under Subpart A and Subpart C and certify to OHRP that an appropriately constituted IRB reviewed the research project and made all other required findings under DHHS regulations at 45 CFR 46.305(a).

The research may not commence until the IRB receives OHRP authorization.

When a Research Subject becomes a Prisoner

1. The Investigator promptly notifies the IRB when a research subject becomes a prisoner (as defined above) while enrolled in a research study.
2. If the research was not initially reviewed and approved per this policy, all research activities involving the now incarcerated prisoner-subject should cease.
3. Before termination of participation, the investigator and the IRB should consider the risks associated with early termination. The Investigator may request that the

subject continue in the research if it is in his/her best interests to remain in the research study while incarcerated.

- All requirements of this policy must be met, including re-review of the study with prisoner representation and, for DHHS-supported research, compliance with Subpart C and certification by OHRP.
 - If some of the requirements of Subpart C cannot be met, but it is in the subject's best interest to remain in the study, keep the subject enrolled and inform OHRP of the decision and the justification.
 - Alternatively, the investigator can explore other mechanisms to continue the intervention outside of a study such as off-label use, etc.
4. Should a subject be **temporarily** incarcerated while participating in the study:
- If the temporary incarceration has no effect on study involvement, keep the subject enrolled.
 - If the temporary incarceration has an effect on study involvement, handle according to steps 1-3 above.

Preparation of a Prisoner Certification Letter to OHRP

The IRB Administrator or his/her designee ensures that all appropriate documentation is provided to OHRP for prisoner certification of DHHS-supported research involving prisoners, including:

- The IRB determination minute which includes references to 45 CFR 46.305 and 46.306 and specifically indicates the applicable category/categories under 45 CFR 46.306(a) (2).
- The IRB-approved protocol summary in sufficient detail to allow OHRP to make its determination
- Any relevant HHS grant application or proposal
- Federal funding agency Program Director's name and contact information
- Any IRB application forms required by the IRB
- Any other information requested or required by the IRB to be considered during initial IRB review
- OHRP also encourages the institution to include the following information in its prisoner research certification letter, to facilitate processing:
 - Federalwide Assurance #
 - Name of designated IRB committee
 - Date(s) of IRB Meeting(s) in which protocol was considered, including a brief chronology that encompasses:
 - Date of initial IRB review
 - Date of Subpart C review

Related Documents

[Convened IRB Meeting Process](#)

[IRBe Applications](#)

References

45 CFR 46 - Protection of Human Subjects

Effective Date

June 3, 2015