

# Special Categories of Research: Prisoners Policy

## Scope

Applies to the Mayo Clinic Human Research Protection Program and Institutional Review Board (IRB) when conducting research that involves prisoners for which Mayo Clinic IRB is the IRB of Record.

## Purpose

To define, in accordance with relevant laws and regulations, additional protections required when biomedical and/or behavioral research involves prisoners as research subjects.

## Policy

### IRB Review of Research

The Mayo Clinic IRB must 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.

### Department of Health and Human Services (DHHS) Supported Research

1. When the IRB approves DHHS-supported research involving prisoners, the Mayo Clinic IRB must prepare an Office for Human Research Protections (OHRP) Prisoner Certification Letter and send it to the DHHS Secretary.
2. The letter must state 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).
3. The IRB must receive OHRP authorization before allowing an investigator to initiate DHHS-supported research involving prisoners. Refer to the section on the [Preparation of a Prisoner Certification Letter to OHRP](#) for additional 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 must request that the IRB review the research project in accordance with this policy.
3. The Investigator must obtain and provide documentation of approval from the detention or correctional facility involved (i.e., prisons, jails, workhouses, etc.) to the IRB.
4. The Investigator must provide any additional documents or materials required for certification to OHRP if the research is DHHS-supported.

5. The Investigator must 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 must be 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 or continuing review 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 to satisfy these requirements.

### **Documentation of IRB Review**

1. When applying the additional protections at 45 CFR 46 Subpart C, IRB records must document:
  - a. The regulatory determinations and related protocol-specific findings relating to the seven additional duties of the IRB under 45 CFR 46.305(a), and
  - b. The permitted category/categories of DHHS-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**

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

## Exemptions

1. Exemptions that generally apply to certain types of research involving human subjects do not apply to research involving prisoners ([45 CFR 46.104](#)).

## Emergency Research Consent Waiver

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

## Epidemiological Research Waiver

1. 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.
2. The IRB must review the DHHS-supported 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\(a\)](#).
3. The research must not commence until the IRB receives OHRP authorization.

## When a Research Subject becomes a Prisoner

1. The Investigator must promptly notify 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 must cease.
3. Before termination of participation, the investigator and the IRB must 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.
  - a. 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.
  - b. 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.
  - c. 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:
  - a. If the temporary incarceration has no effect on study involvement, keep the subject enrolled.
  - b. 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

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

- a. The IRB determination record (e.g., investigator notification, meeting minutes, etc.) referencing 45 CFR 46.305 and 46.306 and specifically indicating the applicable category/categories under 45 CFR 46.306(a) (2).
- b. The IRB-approved protocol summary in sufficient detail to allow OHRP to make its determination.
- c. Any relevant DHHS grant application or proposal.
- d. Federal funding agency Program Director's name and contact information.
- e. Any IRB application forms required by the IRB.
- f. Any other information requested or required by the IRB to be considered during initial IRB review.
- g. OHRP also encourages the institution to include the following information in its prisoner research certification letter, to facilitate processing:
  - i. Federalwide Assurance # (FWA)
  - ii. Name of designated IRB committee
  - iii. Date(s) of IRB Meeting(s) in which protocol was considered, including a brief chronology that encompasses:
    1. Date of initial IRB review
    2. Date of Subpart C review

## Policy Notes

N/A

## Related Procedures

N/A

## Related Documents

[IRBe Sample Applications](#)

## Definitions

**Department of Health and Human Services (DHHS):** The United States Department of Health and Human Services, is a cabinet-level executive branch department of the U.S. federal government created to protect the health of all Americans and providing essential human services. .

**Office for Human Research Protections (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.

**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.

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

## References

[45 CFR 46 - Protection of Human Subjects](#)

## Owner

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## Contact

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## Revision History

Date	Synopsis of Change
06/14/2022	Scheduled review. Transferred to standardized template. Owner & Contact updated
07/10/2019	Scheduled review, update owner to Tammy Neseth.
09/22/2017	Minor revision. Updated the following definitions per Glossary review: Prisoner.
10/12/2016	Reviewed by Policy Governance office. Edits approved by Pam to update to new template at time of annual review. Minor editorial corrections and clarifications.
Unknown	Approval for need to establish document: Unknown