

I. PURPOSE

The purpose of this SOP is to document the CHOP IRB process for ensuring additional safeguards for the protection of prisoners involved in research activities. The additional protections are needed as prisoners may be under constraints because of their incarceration and as such, this could affect their ability to make truly voluntary and uncoerced decisions whether or not to participate as subjects in research.

II. POLICY STATEMENT

It is the policy of the CHOP IRB that research involving prisoners must comply with 45 CFR 46 Subpart C, with one exception; Subpart C will not apply to non-federally funded research where the incarcerated participant was not a prisoner at the time of enrollment into the research. Whenever it is practicable, these subjects may continue to participate in the study that they were enrolled in prior to becoming incarcerated.

Research involving prisoners as participants must comply with the additional protection considerations described in this SOP in order to gain and maintain IRB approval regardless of whether the research participant was a prisoner at the time of enrollment, or became a prisoner after the research commenced.

III. SCOPE

These policies and procedures apply to all IRB staff, IRB members, and researchers and their staff who propose to conduct research that involves prisoners under the auspices of the CHOP IRB.

IV. DEFINITIONS

Chair: A chair for one or more of the convened IRBs.

Minimal Risk for Prisoners: The probability and magnitude of physical or psychological harm is no more than that which is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination, of healthy persons.

Primary and Secondary Reviewer: An IRB member or alternate selected for each full board protocol review (including Initial, Amendment, Reportable Event, and Continuing Review) who is responsible for providing an in depth review of all submitted materials (described in SOP 301) prior to the meeting, documenting the review on the appropriate evaluation form, presenting the review to the full board, highlighting potential issues for IRB consideration, and making a recommendation for action by the IRB.

Prisoner: Any individual involuntarily confined or detained in a penal institution and their ability to leave the institution is restricted. 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. Individuals who are detained in a residential facility for court-ordered substance abuse treatment as a form of sentencing or alternative to incarceration are prisoners (individuals who are receiving non-residential court-ordered substance abuse treatment and are residing in the community are not prisoners).

V. PROCESS


A. Criteria for Initial and Continuing Approval

1. In addition to the composition and quorum requirements described in **SOP 201**, the Chair or designee ensures that the following additional criteria are met for research involving prisoners:
 - (a) At least one member of the IRB is a prisoner representative with appropriate background and experience to serve in that capacity.
 - (1) When research is reviewed by more than one IRB, only one IRB needs to satisfy this requirement.
 - (2) When the convened IRB reviews research involving prisoners, the prisoner representative must participate as a voting member.
 - (b) A majority of the members of the IRB (exclusive of prisoner representatives) shall have no association with the prison(s) involved.
2. The Primary Reviewer will ensure that the Subpart C (Research Involving Prisoners) checklist is completed.
3. In addition to the research review procedures described in the **SOP 105**, the convened IRB approves research involving prisoners as participants only if it finds that the research satisfies all requirements included on the Subpart C checklist.

B. Incarceration of Participants in Federally Funded Research

When a previously enrolled research participant becomes a prisoner and the relevant federally funded research protocol was not reviewed and approved by the IRB in accordance with the review requirements listed above:

1. The principal investigator must promptly notify the IRB.
2. All research interactions and interventions with, and obtaining identifiable private information about, the now-incarcerated prisoner-participant must cease until the IRB can re-review the protocol to ensure that the requirements listed above have been satisfied. In special circumstances in which the investigator asserts that it is in the best interests of the participant to remain in the research while incarcerated, the Chair may determine that the participant may continue to participate in the

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research until the re-review requirements are satisfied.

3. Upon receipt of notification that a previously enrolled research participant has become a prisoner, the IRB should promptly re-review the protocol in accordance with the review requirements listed above if the principal investigator wishes to have the Prisoner-participant continue to participate in the research.
4. CHOP will certify and forward to the HHS Secretary (through OHRP) that the IRB reviewed the research and made seven findings as required by the regulations (45 CFR 46.305(c) and 46.306(a)(1)). Note: OHRP then will determine whether the proposed research involves one of the categories of research permissible under 45 CFR 46.306(a)(2), and if so which one. Following its review of the certification, OHRP will send the institution a letter authorizing the involvement of prisoners in the proposed research, if OHRP determines that the research involves one of the permissible categories. If OHRP determines that the proposed research does not involve one of the permissible categories, it will state in the letter to the institution that such research involving prisoners cannot proceed.
5. If material changes are made to the protocol and unanticipated problem involving risks to subjects or others, a Prisoner Representative will be present during the review.

C. Incarceration of Participants in Non-federally Funded Research

When a previously enrolled research participant becomes a prisoner during the course of study participation and the research is not federally funded, the subject may continue participating as long as it is practicable to meet the requirements of the study. The principal investigator must promptly notify the IRB of the subject's change in status and inform the IRB regarding whether or not the subject will continue to participate.

VI. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.305, 45 CFR 46.306

21 CFR 56.305, 21 CFR 56.306

VII. REFERENCES TO OTHER APPLICABLE SOPS

SOP 105: IRB Review Processes

SOP 501: Vulnerable Subjects

SOP 201: Composition and Management of the IRB

VIII. RESPONSIBILITIES

Title	Responsibility
Director, HSR	Responsible for maintenance of the SOP and assuring there is a prisoner representative present at IRB meetings where research involving prisoners is proposed. For DHHS-funded research, certifies to OHRP the duties of the IRB have been fulfilled.
Chair, CPHS	Responsible for ensuring the Committees adhere to the appropriate regulations regarding Prisoners during their review.

IX. ATTACHMENTS

The IRB's website includes the Review Subpart C (Research Involving Prisoners) on the Reviewer's Forms page:

<https://www.research.chop.edu/services/irb-checklists>

X. REVISIONS:

- 06-10-2010: Revised for minor grammatical edits and consistency across SOPs and to update the URL for the Reviewer's Forms page.
- 01-11-2013: Revised to reflect that CHOP "un-checked the box" on the FWA and added the requirement for OHRP to certify research where a subject become incarcerated while on the study.
- 05-29-2013: Revised to include minor administrative edits
- 09-25-2018: Revised to include minor administrative edits
- 12-13-2022: Revised to reflect current processes.

XI. APPROVAL:

Approval Indicator: Approved by Amy Schwarzhoff and Barbara Engel on 12/13/22
Amy Schwarzhoff, Director, Human Subjects Research and Barbara Engel, Chair, CPHS