

**HRPP STANDARD OPERATING PROCEDURE/POLICY APPROVAL &
IMPLEMENTATION**

OFFICE OF HUMAN SUBJECTS RESEARCH PROTECTIONS

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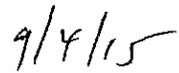
SOP Title: RESEARCH INVOLVING PRISONERS

**Distribution: Scientific Directors; Clinical Directors; Clinical Investigators, IRB
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SOP 14C RESEARCH INVOLVING PRISONERS

INTRODUCTION

This **Standard Operating Policy and Procedure** (SOP) highlights the most common issues that arise at NIH with regard to research with prisoners, but the SOP is not a complete set of regulatory requirements. Therefore, please refer to 45 CFR Subpart C, attached as **Appendix A**, which is hereby incorporated into this SOP.

14C.1 PURPOSE

This SOP discusses requirements for research participation by prisoners. This also includes research that does not target prisoners as subjects and applies whenever any human subject in a research protocol becomes a prisoner at any time during the study.

14C.2 POLICY

Biomedical or behavioral research conducted or supported by **the U.S. Department of Health and Human Services (DHHS)** shall not involve prisoners as subjects unless the research is specifically authorized within 45 CFR 46 Subpart C - Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects (**Appendix A**). Research involving prisoners may not be initiated or continued until there is both **Institutional Review Board (IRB)** approval and **Office for Human Research Protections (OHRP)** approval. This SOP sets forth additional protections required by the NIH's Human Research Protection Program (HRPP) for research involving prisoners as required by 45 CFR 46 Subpart C - Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects. The requirements of this SOP are in addition to those imposed under other subparts of 45 CFR 46 and other relevant SOPs.

- A. Informed consent can be waived or altered in research involving prisoners only in accordance with applicable regulations. However, even if informed consent is waived or altered, subpart C of 45 CFR Part 46 still requires that the subjects be clearly informed in advance that participation in the research will have no effect on their parole, if such notification is relevant. (45 CFR 46.305(a)(6)).
- B. **Secretarial waiver of informed consent in certain emergency research is not available for research involving prisoners (see SOP 12 - Requirements for Informed Consent).**
- C. At NIH, expedited IRB review is not permitted for research involving prisoners as subjects.

- D. The exemptions at 45 CFR 46.101(b) cannot be applied to research involving prisoners.

14C.3 ETHICAL CONSIDERATIONS

Prisoners are considered vulnerable subjects because their incarceration could affect their ability to make voluntary and uncoerced decisions about whether or not to participate in research. Additional safeguards for the protection of prisoners are **therefore** required when they participate in research.

14C.4 DEFINITIONS

(See 45 CFR 46.303)

- A. **Minimal Risk** is 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)).

Note: The definition of minimal risk for prisoner research at 45 CFR 46.303(d) differs from the definition of minimal risk that applies to other research NOT involving prisoners, which is: “minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests” (see 45 CFR 46.102(i)).

- B. **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 that provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing (45 CFR 46.303(c)).

- C. **Secretary** means the Secretary of Health and Human Services and any other officer or employee of DHHS to whom authority has been delegated (45 CFR 46.303(a)).

14C.5 IRB REQUIREMENTS

14C.5.1 ADDITIONAL REQUIREMENTS FOR THE COMPOSITION OF THE IRB

In addition to satisfying the general requirements for NIH IRB membership under 45 CFR 46.107 (see SOP 2 - IRB Membership and Structure and SOP 14A - Research Involving Vulnerable Subjects (General Considerations)), when reviewing any proposed or ongoing research (e.g., at initial review, continuing review, amendments or

unanticipated problems) involving prisoners, the following specific requirements also apply.

- A. A majority of the NIH IRB (exclusive of prisoner members) must have no association with the prison(s) involved, apart from their membership to the IRB. (45 CFR 46.304(a)).
- B. At least one member of the NIH IRB must be a prisoner or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one IRB, only one IRB need satisfy this requirement. (45 CFR 46.304(b)). The prisoner representative is present at the meeting when research on prisoners is reviewed.
- C. Any change in the IRB roster by the addition of a prisoner/prisoner representative must be reported to OHRP through the Office of Human Subjects Research Protection (OHSRP) in accordance with 45 CFR 46.103(b)(3).
- D. The prisoner/prisoner representative counts towards the quorum only when he or she is in attendance and reviewing studies covered by subpart C.

14C.5.2 ROLE AND RESPONSIBILITIES OF THE PRISONER REPRESENTATIVE

- A. The prisoner representative must be a voting member of the IRB.
 - 1. The prisoner representative must review research involving prisoners consistent with **14C.5.1** and **14C 5.3**, and like all IRB members, will focus on the applicable requirements in Subpart C or equivalent protections.
 - 2. The prisoner representative must receive all review materials pertaining to the research (even if there is a primary reviewer).
- B. 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.
 - 1. 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 present in person.
- C. 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 (See **section 14C.7**, below, for the description of the four categories of permitted research with prisoners).

14C.5.3 ADDITIONAL DUTIES OF NIH IRBS REVIEWING RESEARCH INVOLVING PRISONERS

- A. In addition to all other responsibilities prescribed for IRBs under 45 CFR 46 Subpart C, an NIH IRB will review research involving prisoners and approve such research only if it finds that the research under review falls into one of the four categories of research permissible under 45 CFR 46.306(a)2 and complies with 45 CFR 46.305. (See 45 CFR 46.305 and .306 for more information.)

14C.6 NIH HRPP CERTIFICATION TO THE SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES (DHHS)

The NIH shall certify to the Secretary, DHHS that the NIH IRB approval of research involving prisoners has fulfilled the requirements of 45 CFR 46.305 (see 45 CFR 46.305(c) and .306(a)(1)).

- A. Procedure for NIH certification: The NIH OHSRP shall send a copy of the research proposal along with a certification letter signed by the Institutional Official (Deputy Director of Intramural Research (DDIR)) to the DHHS OHRP.
 - 1. For the purposes of this SOP, a research proposal includes the IRB-approved protocol, consent document(s), any relevant grant application or proposal, any IRB application forms or forms required by the IRB, and any other information requested or required by the IRB that was considered during initial IRB review.
- B. Decision by OHRP: NIH research involving prisoners may not begin or be conducted until OHRP provides its approval in writing to NIH on behalf of the Secretary (see 45 CFR 46.306(a)).

14C.7 PERMITTED RESEARCH INVOLVING PRISONERS

The IRB will review research involving prisoners and approve such research only if it finds that the research under review falls into one of the four following categories:

- A. Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects.
- B. Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects.

- C. Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) (see 45 CFR 46.306(a)(2)(iii) for additional procedural requirements).
- D. Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, see 45 CFR 46.306(a)(2)(iv) for additional procedural requirements.

14C.8 WAIVER OF THE APPLICABILITY OF CERTAIN PROVISIONS FOR CERTAIN TYPES OF EPIDEMIOLOGY RESEARCH INVOLVING PRISONERS AS SUBJECTS

The DHHS Secretarial waiver for certain types of epidemiological research functions as a fifth category of permitted research with prisoners under 14C.5.2.A.1 above (see link to Prisoner Research in **References** below).

The criteria for this category are that the research must have as its sole purpose (i) to describe the prevalence or incidence of a disease by identifying all cases, or (ii) to study potential risk factor associations for a disease (61 FR 51531, October 2, 1996). The NIH still must review the research under subpart C of 45 CFR 46 and certify to OHRP that an appropriately constituted IRB has reviewed the proposal and made all other required findings under DHHS regulations at 45 CFR 46.305(a). Prior to initiating any research involving prisoners, **the NIH must receive an authorization in writing from OHRP**. All of the other requirements of subpart C of the regulations apply to research in this category.

Note that research covered by this waiver requires that the IRB approved the research and fulfilled its duties under 45 CFR 46.305(a)(2)-(7) and determined and documented that (i) the research presents no more than minimal risk and no more than inconvenience to the prisoner-subjects, and (ii) prisoners are not a particular focus of the research. The waiver request to OHRP should also note these facts.

14C.9 NON-PRISONER SUBJECTS WHO BECOME PRISONERS DURING THEIR RESEARCH PARTICIPATION

14C.9.1 SUBJECTS ALREADY ENROLLED IN RESEARCH PROTOCOLS

The requirements of this SOP apply also to subjects who are enrolled in ongoing research protocols and who become prisoners during their research participation (see OHRP FAQs **in References** below).

14C.9.2 ACTIONS REQUIRED IF AN ONGOING PROTOCOL WAS NOT REVIEWED UNDER THE REQUIREMENTS OF THIS SOP (SUBPART C, 45 CFR 46) AND AN ALREADY-ENROLLED RESEARCH SUBJECT BECOMES A PRISONER DURING THE COURSE OF THE STUDY

- A. The **Principal Investigator (PI)** must promptly notify the IRB and NIH's OHSRP.
- B. All research interactions and interventions with, and obtaining identifiable private information about, the now-incarcerated prisoner-subject must stop immediately until the requirements of 45 CFR 46 subpart C have been satisfied for the relevant protocol, except as noted in C, below.
- C. The one OHRP exception is that in special circumstances in which the **PI** asserts that it is in the best interests of the subject to remain in the research while incarcerated, the IRB Chair may determine that the subject may continue to participate in the research until the requirement of subpart C (and this SOP) are satisfied.
- D. Upon receipt of notification that a previously enrolled research subject has become a prisoner, the IRB must promptly re-review the protocol in accordance with the requirements of subpart C and this SOP if the investigator wishes to have the prisoner subject continue to participate in the research.
- E. The NIH, through OHSRP, will send a certification to OHRP (see **14C.6.A** above). Research may not resume with the prisoner until OHRP provides a written authorization.

REFERENCES

- A. Guidance on the Involvement of Prisoners in Research: <http://www.hhs.gov/ohrp/policy/prisoner.html>
- B. OHRP Prisoner Research Certification: <http://www.hhs.gov/ohrp/policy/populations/prisoncertlet.html>
- C. OHRP Prisoner Research FAQ: <http://www.hhs.gov/ohrp/policy/faq/prisoner-research/index.html>

LIST OF APPENDICES

Appendix A – 45 CFR 46 Subpart C:

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartc>

APPENDIX A: 45 CFR 46.300 SUBPART C PRISONERS**Subpart C - Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects**

Source: 43 FR 53655, Nov. 16, 1978, unless otherwise noted.

§46.301 Applicability

The regulations in this subpart are applicable to all biomedical and behavioral research conducted or supported by the Department of Health and Human Services involving prisoners as subjects.

Nothing in this subpart shall be construed as indicating that compliance with the procedures set forth herein will authorize research involving prisoners as subjects, to the extent such research is limited or barred by applicable State or local law.

The requirements of this subpart are in addition to those imposed under the other subparts of this part.

§46.302 Purpose

Inasmuch as prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research, it is the purpose of this subpart to provide additional safeguards for the protection of prisoners involved in activities to which this subpart is applicable.

§46.303 Definitions

As used in this subpart:

- (a) *Secretary* means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom authority has been delegated.
- (b) *DHHS* means the Department of Health and Human Services.
- (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.

- (d) *Minimal risk* is 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.

§46.304 Composition of Institutional Review Boards where prisoners are involved

In addition to satisfying the requirements in §46.107 of this part, an Institutional Review Board, carrying out responsibilities under this part with respect to research covered by this subpart, shall also meet the following specific requirements:

- (a) A majority of the Board (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the Board.
- (b) At least one member of the Board shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one Board only one Board need satisfy this requirement.

[43 FR 53655, Nov. 16, 1978, as amended at 46 FR 8366, Jan. 26, 1981]

§46.305 Additional duties of the Institutional Review Boards where prisoners are involved

- (a) In addition to all other responsibilities prescribed for Institutional Review Boards under this part, the Board shall review research covered by this subpart and approve such research only if it finds that:
1. The research under review represents one of the categories of research permissible under §46.306(a)(2);
 2. Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;
 3. The risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;

4. Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the Board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;
 5. The information is presented in language which is understandable to the subject population;
 6. Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and
 7. Where the Board finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.
- (b) The Board shall carry out such other duties as may be assigned by the Secretary.
- (c) The institution shall certify to the Secretary, in such form and manner as the Secretary may require, that the duties of the Board under this section have been fulfilled.

§46.306 Permitted research involving prisoners

- (a) Biomedical or behavioral research conducted or supported by DHHS may involve prisoners as subjects only if:
1. The institution responsible for the conduct of the research has certified to the Secretary that the Institutional Review Board has approved the research under §46.305 of this subpart; and
 2. In the judgment of the Secretary the proposed research involves solely the following:
 - I. Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

- II. Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
- III. Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the FEDERAL REGISTER, of his intent to approve such research; or
- IV. Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the FEDERAL REGISTER, of the intent to approve such research.

Except as provided in paragraph (A) of this section, biomedical or behavioral research conducted or supported by DHHS shall not involve prisoners as subjects.