UNIVERSITY OF SOUTH ALABAMA

IRB SOP 903
Research Involving Prisoners

Purpose

This Standard Operating Procedure (SOP) describes the additional responsibilities and procedures involved when reviewing research that involves prisoners as subjects.

Scope

This SOP applies to all research involving prisoners, regardless of funding source.

Applicability

This policy applies to all biomedical and behavioral research conducted under the auspices of University of South Alabama involving prisoners as subjects.

Definitions

Prisoner: 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)]

Minimal Risk: 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. *Note: This definition of minimal risk differs from that in 45 CFR 46 Subpart A by replacing "harm or discomfort" with "physical or psychological harm" and using "healthy person" as the reference point for the medical, dental or psychological examinations.*

Policy

Potential research subjects who are prisoners are at increased risk for coercion and undue influence as a result of their incarceration. To ensure their participation in research is uncoerced and voluntary, additional protections are afforded this population.

For research involving prisoners as participants, the USA IRB follows federal regulations at 45 CFR 46 Subpart C in addition to those imposed under other USA IRB policies and procedures, ethical considerations and other applicable federal, state and local laws for review and approval regardless of funding source.

The USA IRB approves research involving prisoners by following the "*Investigator Checklist for Research Involving Prisoners*".

1.0 Expedited procedures for review of prisoner research are allowed:

- When research does not involve interaction with prisoners (e.g., record review, existing data) and a determination is made that the research involves no greater than minimal risk for the prison population being studied, or
- To secure approval for minor or administrative modifications.
- Protocols originally approved by the convened IRB and remain active only for data analysis may be eligible for expedited review (expedited category 8c).
- The designated prisoner representative reviews research involving prisoners

2.0 Research conducted or supported by DHHS to involve prisoners, two actions must occur:

2.1 The institution engaged in the research must certify to the DHHS Secretary (through OHRP) that the IRB designated under its assurance of compliance has reviewed and approved the research under 45 CFR 46.305; and

2.2 The DHHS Secretary (through OHRP) must determine that the proposed research falls within the categories of research permissible under 45 CFR 46.306(a)(2).

Procedures

1.0 Investigator Responsibilities

1.1 Investigators are responsible for obtaining and providing documentation of approval from the detention or correctional facility involved (i.e., prisons, jails, workhouses, etc.) to the IRB.

1.2 Investigators must provide any additional documents or materials required for certification to the Secretary (through DHHS OHRP) for federally funded research involving prisoners.

1.3 Investigators may not screen, recruit, or enroll any individual involuntarily confined or detained in a penal institution without written IRB approval. If the biomedical or behavioral research is conducted or supported by DHHS, it also requires review and written approval by the Secretary (through DHHS OHRP) before any research activities may begin, including screening and enrollment.

1.4 If the investigator anticipates that some subjects may become prisoners during the study, submission for prospective IRB review for research involving prisoners should occur.

2.0 IRB Responsibilities

2.1 Composition of the IRB when Prisoners are Involved in Research

2.1.1 When the IRB reviews a protocol involving prisoners as participants, the composition of the IRB must satisfy the following requirements of HHS regulations at 45 CRF 46.304 (a) and (b):

2.1.1.1 A majority of the Board (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the IRB; and

2.1.1.2 At least one voting member of the 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.

2.1.1.3 The prisoner representative may be listed as an alternative member who becomes a voting member when needed.

2.1.2 The IRB should choose as a prisoner representative, a person with a close working knowledge, understanding and appreciation of prison conditions from the prospective of a prisoner. Suitable individuals could include prison chaplains, prison psychologists, prison social workers, other prison service providers, or persons who have conducted advocacy for the rights of prisoners. The IRB must meet the special composition requirements

for all types of review of protocols, including initial review, continuing review, review of protocol modifications, review of reports of adverse events or unanticipated problems involving risk to participants or others, or in the event an individual becomes a prisoner while participating in a research protocol.

2.1.3 The prisoner representative must review research involving prisoners, focusing on the requirements in Subpart C or equivalent protections. The prisoner representative receives all review materials pertaining to the research (same as primary reviewer).

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2.1.5 The prisoner representative must be present at the convened meeting when research involving prisoners is reviewed. 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.

2.1.6 If the prisoner representative is not present, research involving prisoners cannot be reviewed or approved.

2.1.7 When expedited procedures are followed, the prisoner representative serves as a reviewer.

2.1.8 The prisoner representative presents their review either orally or in writing at the convened meeting or in writing if the review is expedited for research involving prisoners.

2.1.9 The IRB must notify OHRP of any change in the IRB roster due to the addition of a prisoner representative. Specifically, the IRB should:

- 2.1.9.1 Notify OHRP of the name and qualifications of the prisoner representative, if the approved IRB roster does not currently reflect this information; and
- 2.1.9.2 Maintain the CV of the prisoner representative serving on the IRB.

2.2 Expedited Review

Expedited procedures for review of prisoner research are only allowed:

- when research does not involve interaction with prisoners (e.g., record review, existing data) and a determination is made that the research involves no greater than minimal risk for the prison population being studied, or
- to secure approval for minor or administrative modifications.
- the review of greater than minor modifications and continuing review, except when expedited review category 8.c. is met, must use the same procedures as initial review.

2.3 Incarceration of Enrolled Subjects

If a participant becomes a prisoner while enrolled in a research study that was not reviewed according to Subpart C and Subpart C applies, the IRB must:

2.3.1 Confirm that the participant meets the definition of a prisoner.
2.3.2 Terminate enrollment or review the research study under Subpart C if it feasible for the participant to remain in the study.
2.3.3 Before terminating the enrollment of the incarcerated participant the IRB should consider the risks associated with terminating participation in the study. If the participant cannot be terminated for health or safety reasons, one of two options are available:
2.3.4 Keep the participant enrolled in the study and review the research under Subpart C. 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.
2.3.5 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.
2.3.6 If a participant is incarcerated temporarily while enrolled in a study:
2.3.6.1 If the temporary incarceration has no effect on the study, keep the participant enrolled.
2.3.6.2 If the temporary incarceration has an effect on the study, handle according to the above guidance.
2.3.7 When a subject becomes a prisoner, if the researcher asserts to the IRB that it is in the best interest of the prisoner-participant to continue to participate in the research while a prisoner, the IRB chair may determine that the prisoner-participant may continue to participate until:
2.3.7.1 the convened IRB can review this request to approve a change in the research protocol

` Otherwise, the IRB chair shall require that all research interactions and interventions with the prisoner-subject (including obtaining identifiable private information) cease

until the convened IRB can review this request to approve a change in the research protocol.

The convened IRB, upon receipt of notification that a previously enrolled human participant has become a prisoner, shall promptly re-review the research protocol to ensure that the rights and wellbeing of the human subject, now a prisoner, are not in jeopardy. The IRB should consult with a subject matter expert having the expertise of a prisoner representative if the IRB reviewing the research protocol does not have a prisoner representative.

2.4 Categories of Research in Which Prisoners May Participate

The IRB must find that the research is permissible in one of the following categories:

2.4.1 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;

2.4.2 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;

2.4.3 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 addition, 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;

2.4.4 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 Categories A and B are considered minimal risk. Minimal Risk is defined as risks normally encountered in the daily lives of non-incarcerated healthy persons, not risks encountered in the daily lives of prisoners.

Research involving items noted in sections 2.4.3 and 2.4.4 above may require DHHS OHRP to have the research reviewed by appropriate experts and may require a notice of intent to approve the research published in the Federal Register.

2.5 IRB Required Findings

When an IRB is reviewing a protocol in which a prisoner is a subject, the IRB must make, in addition to other requirements under 45 CFR 46, subpart A, seven additional findings under 45 CFR 46.305(a), as follows:

(1) the research under review represents one of the categories of research permissible under 45 CFR 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 IRB 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 that 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 IRB 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.

These findings are reviewed by the IRB on the *Investigator Checklist for Research Involving Prisoners*.

2.6 Certification of prisoner research

Institutions that conduct HHS-supported research involving prisoners as human subjects must take several steps to certify that the research is permissible according to federal regulations. The Office of Research Compliance will send a brief certification letter to OHRP that simply includes the certification statement required in 45 CFR 46.305(a) and a statement indicating that the IRB chose one of the four permissible categories of research in 45 CFR 46.306(a)(2). Inclusion of the following information is recommended to expedite the prisoner certification process:

- In addition to the prisoner certification, researchers should submit the protocol application (which includes the protocol and any IRB submission materials, including consent forms) and the grant application(s) (and any grant award updates).

- Prisoner research certification letter, including:

    - OHRP Assurance Number
    - IRB Number for Designated IRB
    - Site(s) where research involving prisoners will be conducted
    - If prisoner research site is engaged in research, provide OHRP Assurance Number
    - DHHS Grant Award Number
    - DHHS Funding Agency Name
    - Funding Agency Grants/Program Officer Name and Phone #
    - Title of DHHS Grant
        - Title of Protocol - *if the same as the title of the grant, please indicate as such* Version Date of Consent Document to be used with “prisoners”
    - Date(s) of IRB Meeting(s) in which protocol was considered including a brief chronology of:
        1. Date of initial IRB review
        2. Date of Subpart C reviews
        3. Type of IRB review
        4. Whether or not this is a special IRB review for prisoner issues
            - Principal Investigator(s)

Regulated Documents

45 CFR 46.101(b)
45 CFR Part 46, Subpart C 46.301-46.306

University Related Documents

SOP 701: Informed Consent
SOP 702: Consent Documentation

Related Forms

Investigator Checklist for Research Involving Prisoners (located in IRBNet forms/templates)

References

Prisoner Research FAQs, DHHS OHRP
Prisoner Involvement in Research (2003), DHHS OHRP
Prisoner Research Certification, DHHS OHRP

HISTORY
Effective Date:
Revisions: November, 2018

Responsible Office:

Office of Research Compliance and Assurance