Florida State University Human Subjects Committee

Standard Operational Procedure (SOP) 7-IRB-26

Title:	Prisoners as Research Subjects
Responsible Executive:	Gary K. Ostrander
Approving Official:	Gary K. Ostrander
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1 INTRODUCTION

The special vulnerability of prisoners makes consideration of involving them as research subjects particularly important. 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. To safeguard their interests and to protect them from harm, special ethical and regulatory considerations apply for reviewing research involving prisoners. Therefore, if a protocol involves the use of prisoners as subjects, both the general IRB policies apply and the special requirements outlined in this SOP apply. The IRB may approve research involving prisoners only if these special provisions are met, in compliance with 45 CFR 46.306.

This SOP applies to all biomedical and behavioral research involving prisoners as subjects when one of more of the following apply:

- The research is sponsored by Florida State University
- The research is conducted by or under the direction of any employee or agent of FSU in connection with his or her institutional responsibilities
- The research is conducted by or under the direction of any employee or agent of FSU using any property or facility of FSU
- The research involves the use of FSU's non-public information to identify or contact human research subjects or prospective subjects

For Department of Defense (DoD) sponsored research, projects involving prisoners of war (POW) is prohibited, which includes any person captured, detained, held or otherwise under the control of DoD personnel.

1.1 Definitions

1.1.1 Prisoner

As used in this SOP, "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.

1.1.2 Minimal Risk

The federal regulations provide a unique definition of "Minimal Risk" as it pertains to prisoners as research subjects, and such definition differs from the definition of minimal risk found in the rest of the federal regulations. In 45 CFR 46.303(d), the definition of minimal risk for research involving prisoners reads as follows: *"Minimal Risk" is defined as 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.*

1.1.3 Prisoner Representative

An IRB member with a close working knowledge of prison conditions and the life of a prisoner. Suitable individuals could include present or former prisoners, prison chaplains, prison psychologists, prison social workers, or other prison service providers; persons who have conducted advocacy for the rights of prisoners; or any individuals who are qualified to represent the rights and welfare of prisoners by virtue of appropriate background and experience. The prisoner representative's qualifications must be evidenced by the CV/resume, which will be kept on file in the Human Subjects Office.

1.1.4 Incidental Prisoner

An incidental prisoner is a person who becomes incarcerated after consenting to participate in a research study.

2 PROCEDURES

2.1 Human Subjects Office Staff Review

As with all submissions, Human Subjects Office Staff will perform a pre-review of research involving prisoners as subjects. In doing so, IRB reviewers will be provided with the results of the pre-review, such as applicable regulations and their requirements as well as preliminary determination of the most appropriate category as outlined in Section **2.6**.

2.2 IRB Review Pathways

2.2.1 Expedited Review

In certain limited circumstances, research involving prisoners as subjects may be eligible for expedited review (See Section **2.3** for details). For the purposes of this SOP, expedited review will include a review by the prisoner representative as per Section **2.5**. The prisoner representative

can be the sole reviewer, or in addition to another reviewer. Either the Chair, the reviewer or the prison representative may forward the revision to full committee review.

2.2.2 Full Board Review

For the purposes of this SOP, full board review of research involving prisoners as subjects will require a primary reviewer as well as a secondary review by the prisoner representative, and following the procedures outlined herein.

2.3 Determination of Review Pathway for All Submissions

2.3.1 Initial Review

2.3.1.1 Eligibility for Expedited Initial Review (not applicable for DHHS or DOD-funded research)

If all of the following conditions are met, the research may be eligible for expedited review as per Section **2.2.1**:

- The research involves no interaction or intervention with prisoners
- The research meets the standard criteria for expedited review
- The research meets the definition of minimal risk for prisoners

2.3.1.2 Initial Full Committee Review

Any project not meeting all of the criteria noted in Section **2.3.1.1** will be routed for full committee review.

2.3.2 Continuing review

Continuing review must be performed using the same process as initial review, unless the research meets the standard criteria for expedited review.

2.3.3 Revisions

Revisions to studies involving prisoners as research subjects (including those initially reviewed at full committee) are reviewed following either of the two following pathways:

2.3.3.1 Minor Changes

Minor changes are eligible to follow the expedited pathway as noted in Section **2.2.1**. Samples of minor changes can include changes to study personnel (not inclusive of a principal investigator change), grammar/spelling corrections, changes to improve clarity, other corrections or changes that do not affect the risk of the study, etc.

2.3.3.2 More than a Minor Change

The full convened committee must conduct the review as noted in Section **2.2.2**. Samples of revisions that would be more than a minor change may include such things as changes to eligibility, substantive changes to the overall study design or consent, change in principal investigator etc., which could affect the risk profile of the study.

2.3.4 Exemption

Exemption from review of research involving prisoners is not allowed. Research that would otherwise be exempt from the requirement that it receive IRB approval is not exempt when the research involves prisoners.

2.4 Special Composition of the IRB in Research Involving Prisoners as Subjects

To review a protocol involving prisoners as subjects, a majority of the IRB (exclusive of prisoner members) shall have no association with the prison involved, apart from their membership on the IRB, and at least one member of the IRB 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 IRB only one IRB need satisfy this requirement.

At least one voting member of the IRB must be a prisoner representative.

2.5 Prisoner Representative Review Procedures

- The prisoner representative must review research projects involving prisoners for compliance with the requirements in Subpart C.
- The prisoner representative must receive all review materials pertaining to the research.
- The prisoner representative must be present at the convened/full board meeting when the research involving prisoners is reviewed, or the research cannot be reviewed and/or approved. The prisoner representative can attend the meeting by phone, video-conference, webinar or in person.
- The prisoner representative must present his/her review (orally or in writing) at the convened meeting of the IRB when the research involving prisoners is reviewed.

2.6 Specific Criteria Required to Approve Research

When reviewing a protocol which involves prisoners as subjects, the IRB must make a determination that the project falls into at least one of the five categories below in order to approve the research:

- 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
- A 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
- Research on conditions particularly affecting prisoners as a class (i.e. 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 of DHHS has consulted with appropriate experts (in medicine, ethics, penology, etc.) and published notice in the Federal Register of the intent to approve such research

- Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject
- If the research includes the assignment of prisoners to control groups that might not benefit from the research, it may only proceed after the Secretary of the HHS has consulted with appropriate experts and published a note in the Federal Register of the intent to approve the research

2.6.1 Required criteria when reviewing prisoner research

The IRB must find all of the following when reviewing prisoner research:

- 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
- The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers
- 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 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.
- The information is presented in language which is understandable to the subject population.
- 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.
- 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

2.6.2 Requirements when research is conducted or supported by HHS

For research conducted or supported by HHS to involve prisoners, two actions must occur. First, the IRB must certify to OHRP that is has reviewed and approved the research under the federal regulations and second, that OHRP must determine that the proposed research falls within one of the categories of permissible research as described in Section **2.6**.

The IRB certification to OHRP should consist of a certification letter stating that the IRB has been constituted properly according to federal regulation, that the IRB considered and made the required seven findings set forth in 45 CFR 46.305(a), and that the IRB "finds that category (insert which category applies) of 45 CFR 46.306 permits this research to go forward with prisoners as human subjects." The certification letter should also provide a brief description of this research sufficient

to allow OHRP to determine whether or not to concur with the IRB, and whether OHRP needs to consult with appropriate experts and publish a Federal Register Notice. The IRB Office should retain a copy of this letter. In addition, OHRP may require that the institution responsible for the conduct of the proposed research also submit a copy of the research proposal (this includes the protocol, any relevant grant application, IRB application forms and any other information requested by OHRP) per 45 CFR 46.115(b).

Should the research involve conditions particularly affecting prisoners as a class, or not satisfy the stipulations in Section **2.6**, the research may proceed only after the Secretary of DHHS has consulted with appropriate experts (in medicine, ethics, penology, etc.) and published notice in the Federal Register of the intent to approve such research, and the IRB has approved the project.

The above requirements do not apply to research that is not HHS conducted or supported.

2.7 Prisoners Who Are Minors

When a prisoner is also a minor (i.e. an adolescent detained in a juvenile detention facility is a prisoner), then the SOP regarding Children in Research (Subpart D) will also apply.

2.8 Incidental Prisoner Subjects

If any human subject in a research protocol becomes a prisoner at any time during the course of the study, this SOP applies. This is necessary because it is unlikely that review of the research and the consent document contemplated the constraints imposed by the future incarceration of the subject.

- If a subject becomes a prisoner after enrollment in research, the principal investigator is responsible for reporting in writing this situation to the IRB immediately
- Promptly upon receiving the principal investigator's notice or otherwise becoming aware of the prisoner status of a subject, the IRB should review the protocol again with a prisoner representative to the IRB. The IRB should take special consideration of the conditions of being a prisoner.
- The IRB should confirm that, when appropriate, the informed consent process includes information regarding when subsequent incarceration may result in termination of the subject's participation by the Investigator without regard to the subject's consent
- Upon this review, the IRB can either approve the involvement of the prisoner subject in the research in accordance with this SOP or determine that this subject must be withdrawn from the research.

2.9 Research involving the Federal Bureau of Prisons

The Federal Bureau of Prisons (Department of Justice) places special restrictions on research that takes place within the Bureau. The IRB should review the regulations at 28 CFR Part 512 when considering such research.

2.10 Documentation of Review

When approving a protocol involving prisoners, both the reviewer and the minutes (if the submission is forwarded to full committee review) must document that the Committee made the findings required above. The IRB must classify research involving prisoners into one of the seven categories described within Section **2.6** above and document their discussions of the risks and benefits of the research study.

2.11 Responsibility of Researchers

Researchers are responsible for ensuring compliance with any applicable laws governing research involving prisoners as subjects, and the regulations of the applicable jurisdiction(s) and of the penal institutions.

JUSTIFICATION FOR THIS SOP

Florida State University Policy 7-IRB-0

45 CFR 46.301-306: "Subpart C"

45 CFR 46.115(b)

28 CFR 512