

I. Policy

A. Introduction

Research involving prisoners can only be approved by an IRB that satisfies the following regulatory requirements in 45 CFR 46.304, as quoted in part below:

1. The majority of the Board (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the Board.
2. 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.

B. Guidance on Additional Requirements of Federal Funding Agencies

Please note that protocols conducted by MUSC and sponsored by any of the following federal agencies

- the Department of Defense (DOD),
- Department of Education,
- Department of Energy,
- Department of Justice (DOJ) / National Institute of Justice (NIJ) and Bureau of Prisons (BOP) or
- Environmental Protection Agency (EPA)

have additional operational and review requirements. Further information available on the [MUSC IRB Resources & Guidance Webpage](http://research.musc.edu/ori/irb/resources.html) (<http://research.musc.edu/ori/irb/resources.html>).

C. ICH – Good Clinical Practice (GCP)

The MUSC IRBs operate in accord with ICH-GCP guidelines only to the extent that they are compatible with FDA and DHHS regulations. CGP standards contained in the ICH document are not regulatory requirements

in the United States and vary from FDA and DHHS regulations. As such, the MUSC IRBs do not voluntarily agree to comply with all of the GCP statements unless requested to do so by sponsors as documented in contractual agreements. The MUSC IRBs comply with most aspects of ICH-GCP, and the MUC policies, procedures and forms require investigators to comply with most ICH-GCP guidance. In addition, protocols following the International Committee on Harmonisation – Good Clinical Practices (ICH-GHP) have additional requirements. Further information available on the [MUSC IRB Resources & Guidance Webpage <http://research.musc.edu/ori/irb/resources.html>](http://research.musc.edu/ori/irb/resources.html)).

D. Incarceration of a Research Subject

If during the course of the research, an individual subject becomes a “prisoner” as defined above, the investigator is required to notify the IRB promptly. At that point the investigator must discontinue all research activities with the subject unless the investigator asserts in writing and the reviewing Chair agree in writing that it is in the best interests of the subject to continue to participate in the research while the research is being re-reviewed by the IRB in accordance with the additional protections for research involving prisoners.

In making this determination, the reviewing Chair will consider (1) whether the research involves an intervention or procedure that holds out a prospect of direct benefit that is important to the health or well-being of the individual and is available only in the context of the research and (2) whether the research can be performed safely while the individual is a prisoner.

E. Prisoner Representative

A qualified “prisoner representative” must review all research proposing inclusion of a prisoner population and be a voting Board member at the convened meeting when a protocol including prisoners is discussed. The prisoner representative must be involved in the initial review, continuing review, review of protocol amendments, and review of unanticipated problems associated with a protocol involving a prisoner population.

F. IRB Deliberation and Documentation

When reviewing a protocol involving prisoners, the IRB must make and document the following findings (45 CFR 46.305(a)) that are in addition to those decisions required of all human research studies:

1. The research represents one of the categories of research permissible under 45 CFR 46.306(a)(2);

2. Any possible advantages gained by the prisoner by participating, when compared to the general living conditions, medical care, quality of food, amenities, and opportunity for earnings in prison, are not of such a magnitude that the individual's ability to weigh the risks of the research against the value of such advantages in the limited choice environment 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. Control subjects must be selected randomly from the group of available prisoners who meet the required characteristics unless the Principal Investigator provides rationale for varying the selection process acceptable to the IRB;
5. The information is presented in language which is understandable to the prisoner population of interest;
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 told in advance that participation in the research will have no effect on parole decisions;
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 have been made for this examination or care, taking in account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

Note: "Certification", i.e. documentation, of these findings must be sent to OHRP; the research cannot proceed until OHRP notifies the IRB in writing of their approval (45 CFR 46.306(a)(2)).

G. Categories of Research Involving Prisoners Allowable under 45 CFR 46.306(a)(2)

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 an inconvenience to the subjects;
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 an inconvenience to the subjects;

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 addiction, and sexual assaults) provided that the study may proceed only after the Secretary, HHS, (through OHRP) 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; or
4. Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health and well being of the subject. When 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, HHS, (through OHRP) 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 (OHRP Guidance on the Involvement of Prisoners in Research, 2003).
5. Epidemiological Research addressing the prevalence, incidence, or risk factors for diseases that might affect prisoners (waiver published in the Federal Register on June 20, 2003 as 68 FR 36929). The research must pose no more than a minimal risk and present no more than an inconvenience to the prisoner participant.

H. Research conducted within the Bureau of Prisons - The Medical University of South Carolina, IRB and researchers and research staff must follow the requirements of 28 CFR 512 including,

1. The project must not involve medical experimentation, cosmetic research, or pharmaceutical testing.
2. The research design must be compatible with both the operation of prison facilities and protection of human subjects. The researcher must observe the rules of the institution or office in which the research is conducted.
3. Any researcher who is a non-employee of the Bureau must sign a statement in which the researcher agrees to adhere to the provisions of 28 CFR 512.
4. All research proposals will be reviewed by the Bureau of Prisons Research Review Board.

II. Definitions

Definitions for the following terms used in this section may be found in HRPP Program Guide Section 1.3 Definitions of Terms:

A. Minimal Risk

B. Prisoner

III. Procedures

A. The Principal Investigator will describe the rationale for including this vulnerable population in the research and specify the applicable permissible category of research involving prisoners, in the human subjects section of the protocol.

B. The IRB administrator and chair will assign the protocol to the primary reviewers; one of the reviewers must be the prisoner representative.

C. Using the “Special Subject Populations – Prisoners” checklist, the Board will determine if the research fits one of the allowed categories, the Board will specifically address the federally mandated issues described under 45 CFR Part 46, subpart C.

D. The Board’s discussion and decisions will be documented in the meeting minutes.

E. If the Board approves the research, the IRB Administrator will prepare the federally required “certification” letter to be sent to OHRP; the letter will be signed by the chair. OHRP also requires a copy of the approved research protocol, any HHS grant application or proposal, the IRB application form, and all other materials submitted to the IRB as requested. The IRB Administrator will notify the Principal Investigator of the status of the approval and will upload the letters to and from OHRP to the eIRB study workarea.

IV. References

A. [Special Subject Populations Checklist - Prisoners](#)