

Research Involving Prisoners	Effective Date	5.8.2000
	Revisions Date	3.9.2023

- 1.0 Purpose:** The purpose of this standard operating practice (SOP) is to establish guidelines for the conduct of research that involves prisoners as participants. This SOP also applies to participants enrolled in a study that subsequently become a prisoner during the study.
- 2.0 Persons Affected:**
- 2.1 Principal investigators (PI) and research team members
 - 2.2 University and Medical Center Institutional Review Board (UMCIRB) members
 - 2.3 UMCIRB staff members
- 3.0 SOP:** Prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and uncoerced decision about whether to participate in research. Because of this limited autonomy, additional safeguards for the protection of prisoners involved in human research activities must be considered. Additional federal regulations must be applied to any research involving prisoners. Research done in the NC prison system must also be reviewed by the North Carolina Department of Public Safety (NC DPS). Prisoner research does not qualify for exempt review.
- 4.0 Definitions:**
- 4.1 **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.
 - 4.2 **Minimal Risk regarding Prisoners** means 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. There are additional elements of the risk/benefit ratio that must be evaluated when considering prisoners as potential participants.
 - 4.3 **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.
 - 4.4 **Categories of permissible research involving prisoners:**
 - 4.4.1 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;
 - 4.4.2 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;
 - 4.4.3 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 addiction, and sexual assaults). If the study is federally funded* 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
 - 4.4.4 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 and the study is federally funded, 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.

*Secretarial consultation and certification are not required if the research is not conducted or supported by HHS, regardless of whether the institution has chosen to extend the applicability of its FWA and subpart C to all research.

5.0 Responsibilities:

5.1 UMCIRB staff are responsible for

- 5.1.1** Providing guidance to researchers about human research involving prisoners.
- 5.1.2** Ensuring that at least one member of the UMCIRB committee that will review new prisoner research is a prisoner or a prisoner representative with appropriate background and experience to serve in that capacity. The prisoner representative will be a voting member of the UMCIRB. A comment has been added to the membership roster indicating that the prisoner representative will only count towards quorum when he or she is in attendance and reviewing studies covered by subpart C.
- 5.1.3** Minor modifications (see Amendment SOP) to an approved study that are eligible for expedited review may be reviewed by the IRB Chair (or designee) of the UMCIRB committee that originally approved the study.

5.2 Investigators have the responsibility to

- 5.2.1** Provide accurate information about the inclusion of prisoners in the electronic IRB application.
- 5.2.2** Seek clarification from the UMCIRB office when unsure about whether the regulations regarding prisoners apply to their study.
- 5.2.3** Communicate with the NC DPS (or DPS/DOC in the state where your research is occurring), if needed, prior to submitting an IRB application.
- 5.2.4** Immediately notify the UMCIRB of any participants currently enrolled in a research study that becomes incarcerated or detained in any fashion, for review of their ongoing participation.

5.3 UMCIRB/UMCIRB Chairperson (or designee) will

- 5.3.1** Utilize prisoner regulations in addition to their usual review according to the Common Rule.
- 5.3.2** Review and approve research involving prisoners only if:
 - 5.3.2.1** The research under review represents one of the categories of the permissible research involving prisoners;
 - 5.3.2.2** 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;
 - 5.3.2.3** The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;
 - 5.3.2.4** 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 UMCIRB 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;

- 5.3.2.5 The information is presented in language which is understandable to the subject population;
- 5.3.2.6 Adequate assurance exists that parole boards (or similar bodies constituted to make parole decisions) 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
- 5.3.2.7 Where the UMCIRB 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.

Date	Change	Reference Section(s)
6.19.2015	Updated to stand-alone document.	All
7.1.2019	Updated office name to UMCIRB throughout; clarified investigator responsibility if research is outside NC	2.0, 5.1, 5.2
2.3.2021	Updated NC DOC to NC DPS and provided Reference link to NC DPS Research guidelines.	3.0, 5.2.3, References
3.9.2023	Update responsibilities for expedited review of minor changes post-IRB approval; clarified voting consideration for prisoner advocate; add clarification about parole boards	5.1, 5.3.2.6

References:

DHHS, OHRP. Code of Federal Regulations. Subpart C: Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects
<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartc>

DHHS, OHRP. Prisoner Research FAQs.
<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/prisoner-research/index.html>

NC DPS. Research Guidelines: <https://www.ncdps.gov/our-organization/adult-correction/research-guidelines>