Western Carolina University
Office of Research Administration
Institutional Review Board Standard Operating Procedures

SOP# 304.1	TITLE: Research Involving Prisoners	Date Effective: 4/10/2024 Last Revision Date: Initial

I. 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. 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 Adult Corrections (DAC). Prisoner research does not qualify for exempt review. All research involving prisoners must be reviewed at a convened meeting with a prisoner representative present to evaluate the project for coercive situations or other issues that may arise from a prisoner perspective.

II. Scope

This procedure is applicable to all members of the WCU IRB.

III. 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 which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

Minimal Risk regarding Prisoners: 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.

Secretary: 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.

Categories of permissible research involving prisoners:

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;

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 (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

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.

IV. Responsibilities

i. *WCU IRB Staff Responsibility*

a. Providing guidance to researchers about human research involving prisoners.

b. Ensuring that at least one member of the WCU IRB 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 WCU IRB. A comment may be added to the membership roster indicating that the prisoner representative will only count towards quorum when they are in attendance and reviewing studies covered by subpart C.

c. Minor modifications (see Modification SOP) to an approved study that are eligible for expedited review may be reviewed by the IRB Chair (or designee) of the WCU IRB committee that originally approved the study

ii. *Investigator Responsibility*

a. Provide accurate information about the inclusion of prisoners in the electronic IRB application.

b. Seek clarification from the WCU IRB office when unsure about whether the regulations regarding prisoners apply to their study.

c. Communicate with the NC DPS (or DPS/DOC in the state where your research is occurring), if needed, prior to submitting an IRB application.

d. Immediately notify the WCU IRB of any participants currently enrolled in a research study that becomes incarcerated or detained in any fashion, for review of their ongoing participation. If a participant becomes a prisoner while enrolled in a research study that was not reviewed according to Subpart C, the investigator must promptly notify the IRB and the IRB shall:

i. Confirm that the participant meets the definition of a prisoner.

ii. Consult with the investigator to determine if it is in the best interests of the participant to continue participation in the study, in part or in full,

and if so, if there are specific study activities which are in the best interests of the subject and should continue until the IRB is able to review the research study under Subpart C.

iii. If the participant should continue, one of two options are available:
    1. Keep the participant enrolled in the study and review the research under Subpart C. If some of the requirements of Subpart C cannot be met or are not applicable (e.g., procedures for the selection of subjects within the prison), 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. Terminate enrollment of 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.

iv. If a participant is incarcerated temporarily while enrolled in a study:
    1. If the temporary incarceration has no effect on the study (i.e., there is no need for study activities to take place during the temporary incarceration), keep the participant enrolled.
    2. If the temporary incarceration has an effect on the study, follow the above guidance.

iii. IRB Chair Responsibility

a. Utilize prisoner regulations in addition to their usual review according to the Common Rule.

b. Review and approve research involving prisoners only if:

i. The research under review represents one of the categories of the permissible research involving prisoners;

ii. 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.

iii. The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;

iv. 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 WCU 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;

v. The information is presented in language which is understandable to the subject population;

vi. 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

vii. Where the WCU 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.

VII. 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