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 whether or not to participate in research. Because of this limited autonomy, additional safeguards for the protection of prisoners involved in human research activities must be taken into account. 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 Corrections (DOC). 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 be reviewing the prisoner research is a prisoner or a prisoner representative with appropriate background and experience to serve in that capacity.

5.1.3 In the event that an item submitted to the UMCIRB can be expedited, ensuring the UMCIRB reviewer is the prisoner advocate member.

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 DOC (or 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 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.

<table>
<thead>
<tr>
<th>Date</th>
<th>Change</th>
<th>Reference Section(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.19.2015</td>
<td>Updated to stand-alone document.</td>
<td>All</td>
</tr>
<tr>
<td>7.1.2019</td>
<td>Updated office name to UMCIRB throughout; clarified investigator responsibility if research is outside NC</td>
<td>2.0, 5.1, 5.2</td>
</tr>
</tbody>
</table>

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.