1.0 Purpose
The purpose of this SOP is to describe the procedure for research involving prisoners.

2.0 Policy
It is the policy of the IRB that the IRB will adhere to Health and Human Services regulations at 45 CFR §46, Subpart C provides for additional protections for prisoners involved in social/behavioral and biomedical research. These special protections include individuals who are prisoners at the time of enrollment in the study, as well as participants that become incarcerated after enrollment in a study. The IRB will apply Subpart C to all research involving prisoners regardless of funding, with one exception described under “Special Circumstances” (See section 2.3 below.)

2.1 Definitions
A. Prisoner is defined by Health and Human Services regulations as 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.

B. Minimal risk in prisoner research is defined by Health and Human Services regulations 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.”

2.2 Permitted Research Involving Prisoners.
Social/behavioral and biomedical research may involve prisoners as participants only if:

A. The IRB has reviewed, approved, and determined that the research falls under one of the categories listed below in Section 2.7. In the case of DHHS-funded research, the IRB also must certify the approval to OHRP as described in 2.9.

B. The proposed research must fall within one of the following categories of permissible forms of research:
   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 participants.

   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 participants.
For the remaining two categories, it should be noted that final approval, as indicated below, rests with the Secretary of Health and Human Services with OHRP acting on behalf of the Secretary. Following IRB approval, the entire research proposal (including the IRB-approved protocol, any relevant Health and Human Services grant application or proposal, consent documents, any IRB application forms, and any other information requested or required by the IRB for initial review) will be submitted to OHRP. OHRP will consult with appropriate experts, including experts in penology medicine and ethics, and publish notice, in the Federal Register, of intent to approve such research. Health and Human Services, through OHRP, will issue its approval in writing to the IRB.

3. Research on conditions particularly affecting prisoners as a class (for example, research on social and psychological problems, such as alcoholism, drug addiction and sexual assault).

4. Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the participant. 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, the study may proceed only after the proposal is reviewed by OHRP (as discussed above).

For research which is not funded by Health and Human Services, neither certification to OHRP nor expert review for Categories 3 and 4 is required. The IRB will only approve research, which fits one or more of the designated categories. In addition, the IRB will, at its discretion, convene an equivalent expert review body to review studies classified as 3 or 4.

2.3 Special Circumstances

A. When a previously enrolled participant becomes a prisoner

When a previously enrolled research participant becomes a prisoner and the relevant research was not reviewed and approved by the IRB in accordance with the requirements of Health and Human Services regulations at 46 CFR §46, Subpart C, the principal investigator must report the situation to the IRB immediately. Upon notification that a previously enrolled research participant has become a prisoner and the principal investigator wishes to have the prisoner continue to participate in the research, the IRB will promptly re-review the protocol in accordance with the requirements of Subpart C (as applicable).

All research activities and interventions for the now incarcerated prisoner-participant must stop until the protocol is reviewed under the requirements of Subpart C, except where the PI can justify that it is in the best interest of the participant to remain in the Health and Human Services-funded research study while incarcerated. The IRB Chair may determine that the participant may continue to participate until all the requirements of Subpart C are satisfied.
B. When a potential participant is an adolescent detained in a juvenile detention facility

If a potential participant is an adolescent detained in a juvenile detention facility, the individual is both a child and a prisoner. In such a case, Health and Human Services regulations at 45 CFR §46 Subpart C (prisoners involved in research) and 45 CFR §46 Subpart D (children involved in research) apply and will be satisfied.

C. When the PI indicates that the proposed participant population may have high risk of incarceration during the course of the study (but currently does not include prisoners)

The IRB may choose to review the proposal under Health and Human Services regulations at 45 CFR §46 Subpart C. However, it should be noted that predetermination of a participant population’s potential for incarceration carries additional risks of violating the rights of justice and respect for persons. The definitions of minimal risk and the risk/benefit analysis may not truly be applicable to the participant population.

2.4 Expedited review of research involving prisoners

Health and Human Services regulations allow expedited review; however OHRP recommends that the convened IRB review all research involving prisoners. Therefore, the IRB will normally not use expedited review for protocols, changes, or continuing review of research involving prisoners.

A. If the expedited review process is used for minor modifications to research, one of the two procedures described in 2.4.C.2 below may be used based on the type of modification.

B. Modifications involving more than a minor change reviewed by the convened IRB

1. The same procedure used for initial review must be used including the responsibility of the prisoner representative to review the modification and participate in the meeting (as described in Section 2.6).

C. Continuing review

1. The same procedure used for initial review must be used for continuing review including the responsibility of the prisoner representative to review the continuing review materials and participate in the meeting (as described in Section 2.6).

   a) If no participants have enrolled, the research may receive continuing review using the expedited procedure under expedited category #8 (See Policy #4.002 Expedited Research).

2. Research involving interaction with prisoners may be reviewed by the expedited procedure, if a determination is made that the research involves no greater than minimal risk for the prison population being studied.

   a) The prisoner representative must concur with the determination that the research involves no greater than minimal risk.
b) The prisoner representative must review the research as a reviewer, designated by the chair or consultant. This may be as the sole reviewer or in addition to another reviewer, as appropriate.

c) Review of modifications and continuing review must use the same procedures for initial review using this expedited procedure including the responsibility of the prisoner representative.

3. Research that does not involve interaction with prisoners (e.g. existing data, record review) may be reviewed by the expedited procedure, if a determination is made that the research involves no greater than minimal risk for the prison population being studied.

a) Review by a prisoner representative is not required.

b) The prisoner representative may review the research as a reviewer or consultant if designated by the IRB chair.

c) Review of modifications and continuing review must use the same procedures as initial review.

D. When a participant is incarcerated temporarily while enrolled in a study

1. If the temporary incarceration has no effect on the study, keep the participant enrolled.

2. If the temporary incarceration has an effect on the study, handle according to the guidance in 2.4.A-2.4.C.

2.5 Research involving prisoners and exemption under 45 CFR §46.301(a).
Health and Human Services regulations do not allow exemption of research involving prisoners (see 45 CFR §46.101(i), footnote 1).

2.6 IRB Membership Requirements
In addition to federal requirement regarding any research involving human participants, the IRB will satisfy the following additional requirements when the research involves prisoners, regardless of funding source:

A. The majority of the members of the IRB will not have an association with the prison(s) involved in the study (excluding the prisoner members).

B. At least one member of the IRB present at the IRB meeting and involved in the review will be a prisoner or a prisoner representative. The prisoner representative will have a close working knowledge, understanding, and appreciation of prison conditions from the perspective of the prisoner.

1. The prisoner representative must be a voting member of the IRB. The prisoner representative may be listed as an alternative member who becomes a voting member when needed.
2. The prisoner representative must review research involving prisoners, focusing on the requirements in Subpart C or equivalent protections. The prisoner representative will receive all review materials pertaining to the research (as will the rest of the committee).

3. The prisoner representative must be present at a convened meeting when the research involving prisoners is reviewed. If the prisoner representative is not present, research involving prisoners cannot be reviewed or approved.

   a) The prisoner representative may attend the meeting by phone, video-conference, or webinar, as long as the representative is able to participate in the meeting as if they were present in person at the meeting.

4. The prisoner representative must present his/her review either orally or in writing at the convened meeting of the IRB when the research involving prisoners is reviewed.

C. The IRB will notify OHRP of any change in the IRB roster by the addition or change of a prisoner representative, as required by Health and Human Services regulations at 45 CFR §46.103(b) (3). The IRB will be aware of the impact of roster changes on quorum requirements under Health and Human Services regulations at 45 CFR §46.108(b).

D. The IRB is aware that the special composition requirement for research involving prisoners involves not only the initial review of the protocol, but also continuing review, protocol/consent amendments, review of reports of unanticipated problems involving risks to participants, and all other IRB matters pertaining to the protocol.

2.7 IRB Findings
The IRB will follow all pertinent federal regulations pertaining to human participant research, as well as make seven additional findings for research involving prisoners regardless of funding source:

A. The research represents one of the categories permissible under Health and Human Services regulations pertaining to research involving prisoners.

B. Any possible benefits to the prisoner through his/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/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.

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

D. Procedures for the selection of participants 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 IRB justification in writing for following some other procedures, control participants will be selected randomly from the group of
available prisoners who meet the characteristics needed for that particular research project.

E. The information is presented in language which is understandable to the participant population.

F. Adequate assurance exists that parole boards will not take into account a prisoner’s participation in 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.

G. If 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 prisoner’s sentences and for informing participants of this fact.

2.8 Documentation of IRB Findings
Per federal regulations, the IRB will prepare and maintain adequate documentation of IRB activities. For the purposes of Subpart C, the IRB activities include making the specific findings required under Health and Human Services regulations along with protocol-specific findings justifying those determinations. OHRP accepts documentation of protocol-specific information justifying each IRB finding required under 45 CFR §46.305(a) to be one way of adequately documenting the IRB activities required under Subpart C. The IRB will follow the aforementioned OHRP guidance.

2.9 Health and Human Services Funded Research - Notification To OHRP

A. The IRB is responsible for providing certification to OHRP that the IRB has made the seven findings applicable to Health and Human Services funded research involving prisoners. The IRB will send OHRP a certification letter to this effect, which includes:

1. The name and address of the Institution
2. Identification of the research protocol and relevant Health and Human Services grant application or protocol.
3. A copy of all paperwork necessary for IRB initial review (IRB-approved protocol, relevant Health and Human Services grant application or proposal, IRB application, consent(s), etc.).
4. Verification of the presence of a prisoner representative during consideration of the study.
5. Verification of the seven required findings (listed above).
6. Determination that the research meets one of the above categories of research permissible by federal regulations.

B. Prisoner research certification letters should be mailed to the OHRP Prisoner Research Contact person in the Office for Human Research Protections at the Department of Health and Human Services.
2.10 Department of Defense regulated research involving prisoners

A. Research involving prisoners of war is prohibited.

B. The IRB must be aware of the definition of “prisoner of war” for the Department of Defense component granting the addendum.

Administrative Approval:

___________________________________  ________________________________________
William Thomas, Ph.D.                  Kimberly Andrews Espy, M.D.
IRB Chair                               Associate Vice Chancellor for Research