1.0 POLICY

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1.1 It is UA policy that research will include additional safeguards to protect the rights and welfare of subjects when some or all of the subjects involved in research are prisoners. A prisoner is defined as any individual involuntarily confined or detained in a penal institution or who is detained pending arraignment, trial, or sentencing. This definition also includes any individual who enrolls in a research study, and then becomes a prisoner while in the study. All research involving prisoners, regardless of the funding source, must receive review and approval under 45 CFR Part 46, Subpart C before research is initiated.

1.2 IRB membership will include member representation with expertise in selected vulnerable populations routinely reviewed by the IRB, such as prisoners. The ORC staff will screen IRB membership applicants for expertise with vulnerable categories to insure that designated representatives are available to review research involving prisoners.

1.3 Research involving prisoners cannot be considered for exempt status.

1.4 The IRB will consider applications involving prisoners for expedited review if the research involves the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. The prisoner representation will be included in this review. However, because of the vulnerability of prisoners, applications that do not meet these standards must be reviewed at a convened meeting of the IRB. See http://www.hhs.gov/ohrp/prisonerfaq.html#q17.

1.5 Research involving the use of prisoners as participants must include the following additional IRB requirements:

1.5.1 The research project complies with federal regulations or requirements for the inclusion of prisoners as participants;

1.5.2 At least one IRB member must be a prisoner or prisoner advocate, with the appropriate background or experience to serve in that capacity and shall be present at the IRB meeting. A majority of the IRB (exclusive of prisoner members) have no association with the prison involved, apart from their membership on the IRB.
1.6 The IRB may approve research involving prisoners only if the research falls into one of the following categories:

1.6.1 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;

1.6.2 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; [45 CFR 46.306 (a)(1)(B)];

1.6.3 Research on conditions particularly affecting prisoners as a class (e.g., vaccine trials on hepatitis which is more prevalent in prisons) provided that the Secretary, HHS, or designee has published notice in the Federal Register of its intent to approve such research. [45 CFR 46.306 (a)(1)(C)];

1.6.4 Research under review has the intent and reasonable probability of improving the health and well-being of the participant. [45 CFR 46.306 (a)(1)(D)]

1.6.5 Advantages accruing to the prisoner through participation in the research, 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 prisoner's ability to weigh the risks and benefits of the research in the limited-choice environment of the prison is impaired.

1.6.6 The risks involved in the research are commensurate with risk that would be accepted by non-prison volunteers.

1.6.7 Selection procedures are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the investigator provides the IRB justification in writing for following some other procedures, all control participants must be selected randomly from the group of eligible prisoners for the research project.

1.6.8 Information given to participants is presented in clear and understandable language appropriate to the population.

1.6.9 Adequate assurance is provided and communicated to the prisoner that participation in the study investigation will have no effect on his/her parole.

1.7.0 Adequate provision is made for post-participation care, while the participants are still prisoners. In addition, the provision of such care will take into account the varying lengths of prison sentences, and for informing participants of this fact.

1.7 If the IRB determines that the study meets criteria in section 1.5, the determination will be documented and a copy of the research proposal will be forwarded to the Office of Research Compliance (ORC). The study cannot be initiated unless the ORC determines the proposed research involves at least one of the categories of research permissible under 45 CFR 46.306(a)(2), and if so, which one.

1.8 When Participants Become Prisoners During a Research Protocol
1.8.1 This policy will become effective whenever a human participant in a research becomes a prisoner at any time after the study begins. It is necessary since it is unlikely the initial review and initial consent document anticipated the constraints imposed by the possible future incarceration of participants.

1.8.2 If a study participant becomes a prisoner after enrolling in a research study, all research interaction and data collection regarding the participant must cease, and the principal investigator must immediately report the situation in writing to the IRB. In special circumstances, if the investigator asserts it is in the best interest of the participant to remain in the research study while incarcerated, the IRB chairperson may determine that the participant may continue to participate in the research until all requirements of Subpart C are satisfied.

1.8.3 At the earliest opportunity after receiving the investigator's notice, the IRB will review the protocol again with a prisoner representative as a member of the IRB. The IRB should take special consideration of the conditions of being a prisoner.

1.8.4 The IRB can either approve the involvement of the prisoner participant in the research in accordance with this policy or determine that the participant must be withdrawn from the research.

1.8.5 Additionally, the IRB should confirm that the informed consent document includes information regarding the possibility of subsequent incarceration; and that such an occurrence may result in the participant’s termination from the study regardless of the participant’s prior consent.

1.9 The Human Research Protections Program and IRB shall educate investigators and IRB members about new and evolving guidelines for review of research involving prisoners.

2.0 Responsibility

2.1 The Vice President for Research is ultimately responsible for this policy. Enabling parties include ORC Administrative Staff, the IRB Chairs and members, investigators, and faculty supervisors of student research.

2.0 PROCEDURE

2.1 Screening and Educational Guidance

2.1.2 The principal investigator identifies within the IRB review application that the research study will involve the use and participation of prisoners and justifies their use.

2.1.3 The investigator completes FORM : RESEARCH INVOLVING PRISONERS and attaches it to the IRB application.

2.1.4 Upon receipt of the IRB review application, ORC staff will assess the completeness of the application using FORM: COMPLETENESS OF THE IRB APPLICATION and
conducts a preliminary screening to determine the proposed research study involves the use of prisoners as study participants and that the form RESEARCH INVOLVING PRISONERS has been completed. Subsequently, the ORC staff will provide IRB members (as necessary or requested) appropriate regulatory or educational materials applicable to prisoners as vulnerable subjects for guidance during their review.

2.1.5 The ORC, IRB chair, or designee will request a consultant review if it is determined additional expertise is needed prior to the Initial Full Review or the Continuing Review process.

2.1.6 Applications involving research with prisoners, whether expedited or for full board review, will always be assigned to the Prisoner Representative for primary review.

2.2 Review Process

2.2.1 The IRB will review the application using the FORMS: IRB CHECKLIST FOR REVIEWERS AND INVESTIGATORS and RESEARCH INVOLVING PRISONERS for prisoner research and determine whether the study protocol includes the enrollment and participation of prisoners and whether appropriate safeguards have been considered and are in place. Information of special significance for research involving prisoners includes:

2.2.1.2 The statement or appearance that prisoners have been targeted as research subjects because they are a readily available clustered population

2.2.1.3 Inclusion and exclusion criteria

2.2.1.4 Identification of eligible prospects (the use of wardens or guards to select prospects or present availability of the study to them)

2.2.1.5 Specific laws governing the State of Alabama applicable to specific population groups which may have a bearing upon the final approval of the research protocol (e.g., emancipated individuals, legally authorized representatives, age of majority for research consent, etc.)

2.2.1.6 Protection of privacy and confidentiality, within the constraints of the prison system

2.2.1.7 Incentives

2.2.1.8 Reading level of the consent document

2.2.1.9 Safety of the investigator, particularly if the investigator is a student.

2.2.1.10 Whether approval for one year is adequate or whether the project should be reviewed more frequently based on the nature of the research and the level of risk involved.
2.3 Documentation of IRB Discussions and Decisions

2.3.1 The IRB minutes will describe whether or not the IRB members agree with the acknowledgement of risks and the adequacy of safeguards described in the investigator’s protocol, the category of risk represented by the research, any modifications required by the board, and the discussion of any controverted issues at its fully convened meetings in order to verify that it has effectively addressed research protection for prisoners.

2.3.2 ORC staff will document in the minutes, specific findings or IRB determinations in accordance with IRB policy. The IRB does not need to reconsider pre-determined subjects during subsequent reviews, unless changes to the protocol dictate otherwise.

3.0 REFERENCES

3.1 The Belmont Report

3.2 45 CFR 46: Subparts A, B, C, D

3.3 45 CFR 46.101, 46.115 (B), 46.116, 46.122

3.4 21 CFR 50: Subpart D 50.51, 50.52, 50.53, 50.54, 50.55, 50.56.

3.5 21 CFR 56.111

3.6 DOJ: 28 CFR 512.11 (4,5)

4.0 RELATED SECTIONS

FORM: Application for Research Involving Prisoners