1.0 POLICY

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.

1.1.1. Investigators are responsible for meeting any special requirements of federal funders such as the EPA, Department of Justice, and Department of Defense for research on prisoners. For example, the Department of Justice requires that the researcher has academic preparation or experience in the area of study of the proposed research, identifies the specific resources required from the Bureau of Prisons, and assumes responsibility for the actions of any staff member or contractor on the study.

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 ensure 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](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)]

1.7. When the IRB is reviewing a protocol in which a prisoner will be a subject, the IRB must find and document justification that six additional conditions are met:

1.7.1. 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.

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

1.7.3. 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.

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

1.7.5. Adequate assurance is provided and communicated to the prisoner that participation in the study investigation will have no effect on his/her parole.
1.7.6. 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.

1.8. 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 for 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.

1.9. When Participants Become Prisoners during a Research Protocol

1.9.1. 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.

1.9.2. 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.

1.9.3. 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.

1.9.4. 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.

1.9.5. 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.

1.9.6. When research is conducted within the Bureau of Prisons, the project must have an adequate research design and contribute to the advancement of knowledge about corrections.

1.10. Research Conducted within the Bureau of Prisons

1.10.1. For research conducted within the Bureau of Prisons, the University, IRB, researchers, and research staff must follow the requirements of 28 CFR 512, including:
1.10.1.1 The project must not involve medical experimentation, cosmetic research, or pharmaceutical testing.

1.10.1.2 The research design must be compatible with both the operation of prison facilities and protection of human subjects. The researcher must observe the rules of the institution or office in which the research is conducted.

1.10.1.3 Any researcher who is a non-employee of the Bureau must sign a statement in which the researcher agrees to adhere to the provisions of 28 CFR 512.

1.10.1.4 All research proposals will be reviewed by the Bureau Research Review Board.

1.10.2 Implementation of Bureau programmatic or operational initiatives made through pilot projects is not considered to be research.

1.10.3 The Department of Justice requires that the researcher has academic preparation or experience in the area of study of the proposed research, identifies the specific resources required from the Bureau of Prisons, and assumes responsibility for the actions of any staff member or contractor on the study.

1.10.4 The investigator must assume responsibility for actions of any person engaged to participate in the research project as an associate, assistant, or subcontractor to the researcher.

1.10.5 The selection of participants within any one organization must be equitable.

1.10.6 Incentives may not be offered to help persuade inmate participants to participate. However, soft drinks and snacks to be consumed at the test setting may be offered.

1.10.7 Reasonable accommodations such as nominal monetary re-compensation for time and effort may be offered to non-confined research participants who are both:

1.10.7.1 No longer in Bureau of Prisons custody;

1.10.7.2 Participating in authorized research being conducted by Bureau employees or contractors.

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

1.12 Responsibility

1.12.1 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

2.1.1. 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.

2.1.2. The investigator completes *Form: Research Involving Prisoners* and attaches it to the IRB application.

2.1.3. 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.

2.1.4. 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.

2.1.5. 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 *Form: IRB Checklist for Reviewers and Investigators* and *Form: 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:

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

2.2.1.2. Inclusion and exclusion criteria;

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

2.2.1.4. 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.).
2.2.1.5. Special requirements of funders, such as the EPA, the Department of Defense, or the Department of Justice;

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 within 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.

2.4. For research involving prisoners reviewed by the convened IRB:

2.4.1. 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.

2.4.2. The prisoner representative must review research involving prisoners, focusing on the requirements in Subpart C or equivalent protections. The prisoner must receive all review materials pertaining to the research (same as primary reviewer).

2.4.3. 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.

2.4.4. If the prisoner representative is not present, research involving prisoners cannot be reviewed or approved.

2.4.4.1. 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.
2.4.5. Minor modifications to research may be reviewed using the expedited procedure described below, using either of the two procedures described based on the type of modification.

2.4.6. Modifications involving more than a minor change reviewed by the convened IRB must use the same procedures for initial review, including the responsibility of the prisoner representative to review the modification and participate in the meeting (as described above).

2.4.7. Continuing review must use the same procedures for initial review including the responsibility of the prisoner representative to review the continuing review materials and participate in the meeting (as described above).

2.4.7.1. If no participants have been enrolled, the research may receive continuing review using the expedited procedure under expedited category #8.

2.5. For research involving interaction with prisoners reviewed by the expedited procedure:

2.5.1. 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.

2.5.2. 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.

2.5.3. The prisoner representative must concur with the determination that the research involves no greater than minimal risk.

2.5.4. 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.

2.6. For research that does not involve interaction with prisoners (e.g. existing data, record review) reviewed by the expedited procedure:

2.6.1. Research that does not involve 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 prison population being studied.

2.6.2. Review by a prisoner representative is not required.

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

2.6.4. Review of modifications and continuing review must use the same procedures as initial review.
2.7. If a participant becomes a prisoner while enrolled in a research study that was not reviewed according to Subpart C:

2.7.1. When Subpart C applies:

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

2.7.1.2. If the participant cannot be terminated for health or safety reasons

2.7.1.2.1. 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, 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.

2.7.1.3. Remove the participant from the study and keep the participant on the study intervention under an alternate mechanism such as compassionate use, off label use, off label use, etc.

2.7.1.4. Make a decision whether it is feasible for the participant to remain in the study

2.8. If a participant becomes incarcerated temporarily while enrolled in a study:

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

2.8.2. If the temporary incarceration has an effect on the study, handle according to the above guidance.

2.9. For research conducted within the Bureau of Prisons, the University, IRB, researchers and research staff must follow the requirements of 28 CFR 512, including:

2.9.1. The project must not involve medical experimentation, cosmetic research, or pharmaceutical testing;

2.9.2. The research design must be compatible with both the operation of prison facilities and protection of human subjects. The researcher must observe the rules of the institution or office in which the research is conducted.

2.9.3. Any researcher who is a non-employee of the Bureau must sign a statement in which the researcher agrees to adhere to the provisions of 28 CFR 512.

2.10. When following Environmental Protection Agency regulations:

2.10.1. EPA prohibits research involving the intentional exposure of pregnant women, nursing women, or children to any substance. The EPA requires application of 40 CFR 26 Subparts C and D to provide additional protections to pregnant
women and children as participants in observational research (i.e., research that does not involve intentional exposure to any substance).

2.10.2. EPA policy requires submission of IRB determinations and approval to the EPA human subjects research review official for final review and approval before the research can begin.

2.10.3. For research not conducted or supported by any federal agency that has regulations for protecting human research participants and for which the intention of the research is submission to the EPA, the EPA regulations protecting human research participants apply, including:

2.10.3.1. EPA extends the provisions of the 40 CFR 26 to human research involving the intentional exposure of non-pregnant, non-nursing adults to any substance;

2.10.3.2. EPA prohibits the intentional exposure of pregnant women, nursing women, or children to any substance.

2.11. For National Institute of Justice Funded Research

2.11.1. A copy of all data must be de-identified and sent to the National Archive of Criminal Justice Data, including copies of the informed consent document, data collection instruments, surveys, or other relevant research materials.

2.11.1.1. At least once a year, the investigator shall provide the chief, Office of Research and Evaluation, with a report on the progress of the research.

2.11.1.2. At least 12 working days before any report of findings is to be released, the investigator shall distribute one copy of the report to each of the following: the chairperson of the Bureau Research Review Board, the regional director, and the warden of each institution that provided data or assistance. The investigator shall include an abstract in the report of findings.

2.11.1.3. In any publication of results, the investigator shall acknowledge the Bureau’s participation in the research project.

2.11.1.4. The investigator shall expressly disclaim approval or endorsement of the published material as an expression of the policies or views of the Bureau.

2.11.1.5. Prior to submitting for publication, the results of a research project conducted under this subpart, the investigator shall provide two copies of the material, for informational purposes only, to the Chief, Office of Research and Evaluation, Central Office, Bureau of Prisons.

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
3.5. 21 CFR 50: Subpart D 50.51, 50.52, 50.53, 50.54, 50.55, 50.56
3.6. 21 CFR 56.111
3.8. DoD: DoDD 3216.2, Para 4.4.1, 4.4.2; SECNAVINST 3900.39, para 4.4.1, para 6a(6), para 6a (3); 10 U.S.C. 980
3.9. EPA: 40 CFR 26 Subparts C and D

4.0 RELATED SECTIONS

4.1. FORM: Application for Research involving Prisoners