This policy describes the requirements of the U.S. Department of Justice Bureau of Prisons and National Institute of Justice related to the protection of human subjects in research.

### Bureau of Prisons

The U.S. Department of Justice provides additional requirements when research is conducted within the Bureau of Prisons (BOP). This policy addresses the applicability of the BOP requirements to human subject research reviewed by the Michigan State University (MSU) Institutional Review Boards (IRB).

General provisions for the protection of human subjects in research are codified in 28 CFR 46 and are applicable to research conducted in the BOP. The BOP encompasses the federal prisons. There are also additional requirements codified in 28 CFR 512, such as requirements to obtain approval to conduct research within the BOP and responsibilities of the BOP staff. Even if the research is determined to be exempt under 28 CFR 46 (or 45 CFR 46), the requirements in 28 CFR 512 are applicable. These requirements apply regardless of funding source and are applicable to research involving inmates or BOP staff. In addition, each BOP facility may have unique requirements for human research. These requirements do not apply to state prison systems under the jurisdiction of the States. Implementation of Bureau programmatic or operational initiatives made through pilot projects is not considered to be research.

In addition to MSU IRB review and approval, proposed research must also be reviewed and approved by the BOP (e.g., 28 CFR 512.13, 28 CFR 512.14). A copy of the research proposal submitted to the BOP for review, the informed consent statement, and the approval letter from the BOP Director or the Assistant Director (if approval authority is delegated) should be submitted with the MSU IRB application. Situations in which the BOP approval cannot be obtained until after MSU IRB approval is obtained will be handled on a case by case basis by the IRB administrator. At the time of MSU IRB renewal, the progress reports required by the BOP (28 CFR 512.19) should be submitted to the MSU IRB. However, if the progress reports indicate noncompliance or unanticipated problems involving risks to subjects or others, they should be reported to the IRB in accordance with the Human Research Protection Program (HRPP) Manual 4-8 “Reporting.” See HRPP Manual 9-1 “Unanticipated Problems Involving Risks to Subjects or Others” and 9-2 “Noncompliance” for guidance. The MSU IRB must also be promptly notified if the BOP Director suspends or terminates the research study. See HRPP Manual 4-8 “Reporting” for policies and procedures on reporting.
Requirements for Research Studies and Researchers
There are additional requirements for research studies and researchers when conducting research in the BOP. These requirements will be assessed by the BOP during their review. MSU researchers should be aware of these requirements and incorporate them into their study as appropriate.

Research conducted in the BOP must meet the following criteria:
1. In all research studies the rights, health, and human dignity of individuals involved must be respected.
2. The study must have an adequate research design and contribute to the advancement of knowledge about corrections.
3. The study must not involve medical experimentation, cosmetic research, or pharmaceutical testing.
4. The study must:
   a. Minimize the risks to subjects
   b. Risks to subjects must be reasonable in relation to anticipated benefits
   c. Selection of subjects within any one institution must be equitable
   d. When applicable, informed consent must be sought and documented (see Informed Consent Section below)
5. Incentives may not be offered to help persuade inmate subjects to participate.
   a. However, soft drinks and snacks to be consumed at the test setting may be offered.
   b. Reasonable accommodations such as nominal monetary recompense for time and effort may be offered to non-confined research subjects who are both:
      i. No longer in the BOP custody; and
      ii. Participating in authorized research being conducted by Bureau employees or contractors
6. Researcher must have academic preparation or experience in the area of study of the proposed research.
7. Researcher must assume responsibility for actions of any person engaged to participate in the research study as an associate, assistant, or subcontractor to the researcher.
8. Except as noted in the informed consent statement to the subject, the researcher must not provide research information which identifies a subject to any person without that subject’s prior written consent to release the information. For example, research information identifiable to a particular individual cannot be admitted as evidence or used for any purpose in any action, suit, or other judicial, administrative, or legislative proceeding without the written consent of the individual to whom the data pertains.
9. The researcher must adhere to applicable provisions of the Privacy Act of 1974 and regulations pursuant to this Act.
10. 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.
11. Any research who is a non-employee of the Bureau must sign a statement in which the researcher agrees to adhere to the provisions of this sub-part.

12. Except for computerized data records maintained at an official Department of Justice site, records which contain nondisclosable information directly traceable to a specific person may not be stored in, or introduced into, an electronic retrieval system.

13. If the researcher is conducting a study of special interest to the Office of Research and Evaluation (ORE), the researcher may be asked to provide ORE with the computerized research data, not identifiable to individual subjects, accompanied by detailed documentation. These arrangements must be negotiated prior to the beginning of the data collection phase of the study.

14. The researcher must submit planned methodological changes in a research study to the IRB for approval, and may be required to revise study procedures in accordance with the new methodology.

Under limited circumstances (requests from federal agencies, the Congress, the Federal judiciary, or State or local governments to collect information about areas for which they are responsible and requests by private organizations for organizational rather than personal information from Bureau staff), exceptions to the requirements described above be approved by the ORE.

Research Proposal
Certain information must be provided when submitting a research proposal to the BOP. This includes a statement regarding assurances and certification required by 28 CFR 46 (if applicable), a summary statement, and a comprehensive statement.

The research proposal must include a summary statement which includes:
1. Name and current affiliation(s) of the researcher(s);
2. Title of the study;
3. Purpose of the study;
4. Location of the study;
5. Methods to be employed;
6. Anticipated results;
7. Duration of the study;
8. Number of subjects (staff or inmates) required and amount of time required from each; and
9. Indication of risk or discomfort involved as a result of participation

The research proposal must also include a comprehensive statement which includes:
1. Review of related literature;
2. Detailed description of the research method;
3. Significance of anticipated results and their contribution to the advancement of knowledge;
4. Specific resources required from the Bureau;
5. Description of all possible risks, discomforts, and benefits to individual subjects or a class of subjects, and a discussion of the likelihood that the risks and discomforts will actually occur;
6. Description of steps taken to minimize any risks described (#5);
7. Description of physical and/or administrative procedures to be followed to:
   i. Ensure the security of any individually identifiable data that are being collected for the study, and
   ii. Destroy research records or remove individual identifiers from those records when the research has been completed;
8. Description of any anticipated effects of the research study on institutional programs and operations; and
9. Relevant research materials such as vitae, endorsements, sample informed consent statements, questionnaires, and interview schedules.

Informed Consent
A written informed consent statement must be provided to each subject (staff or inmate) before the research begins. For researchers who are non-employees, the subject’s signature is required on the statement. The signed document is then submitted to the chairperson of the local research review board appointed by the warden (this may not be the IRB). However, if the researcher can demonstrate that the only link to the subject’s identity is the signed statement of informed consent or that there is significantly more risk to the subject if the statement is signed, the signature requirement may be waived. For researchers who are employees of the Bureau, the subject’s signature is required on the statement when the subject’s activity requires something other than response to a questionnaire or interview or the Chief, ORD, determines the research study or data collection instrument is of a sensitive nature.

The written informed consent statement must contain the following:
1. Identification of the principal investigator(s)
2. Objectives of the research study
3. Procedures to be followed in the conduct of the research
4. Purpose of each procedure
5. Anticipated uses of the results of the research
6. A statement of benefits reasonably to be expected
7. A declaration concerning discomforts and risk, including a description of anticipated discomfort and risk
8. A statement that participation is completely voluntary and that the subject may withdraw consent and end participation in the study at any time without penalty or prejudice (the inmate will be returned to regular assignment or activity by staff as soon as practicable)
9. A statement regarding the confidentiality of the research information and exceptions to any guarantees of confidentiality required by federal or state law. For example, a researcher may not guarantee confidentiality when the subject indicates an intent to commit future criminal conduct or harm himself / herself or someone else, or if the subject is an inmate, indicates an intent to leave the facility without authorization.
10. A statement that participation in the research study will have no effect on the inmate subject’s release date or parole eligibility
11. An offer to answer questions about the research study
12. Appropriate additional information as needed to describe adequately the nature and risks of the research.

The informed consent requirements described above may be incorporated into a consent document that contains elements of consent required by 28 CFR 46.116.

Access to Records
28 CFR 512 also limits access to the BOP records. Employees, including consultants of the Bureau who are conducting authorized research studies, shall have access to records relating to the subject which are necessary to the purpose of the research study without obtaining the subject’s consent. A non-employee is limited in access to information available under the Freedom of Information Act (5 U.S.C. 552). However, a non-employee may receive records in a form not individually identifiable when advance adequate written assurance that the record will be used solely as a statistical research or reporting record is provided to the agency (5 U.S.C. 552a(b)(5)).

Reporting, Publication, and Copyright
28 CFR 512 provides additional requirements for reporting, publication, and copyright that impact MSU researchers. At least once a year, the researcher shall provide the Chief, Office of Research and Evaluation, with a report on the progress of the research.

At least 12 working days before any report of findings is to be released, the Researcher 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 Researcher shall include an abstract in the report of findings.

The regulations state that a researcher may publish in book form and professional journals the results of any research study conducted under 28 CFR 512. However, in any publication of results, the researcher must acknowledge the Bureau’s participation in the research study and expressly disclaim approval or endorsement of the published material as an expression of the policies or views of the Bureau. The researchers must also provide two copies of the material, for informational purposes only, to the ORE Chief prior to submitting for publication the results of a research study conducted under 28 CFR 512.

As a precondition to conduct research under 28 CFR 512, a non-employee shall grant in writing to the Bureau a royalty-free, non-exclusive, and irrevocable license to reproduce, publish, translate, and otherwise use and authorize others to public and use original materials developed as a result of research conducted under 28 CFR 512. Subject to the royalty-free, non-exclusive and irrevocable license reserved by the BOP to produce, publish, translate and use such materials, a non-employee may copyright original
materials developed as a result of research conducted under 28 CFR 512. An employee of the BOP may not copyright any work prepared as part of his/her official duties.

Contact MSU Technologies if you have any questions about publication or copyright requirements of the BOP.

**National Institute of Justice Funded Research**
The following requirements are applicable to research that is funded by the National Institute of Justice (NIJ):

1. All research studies are required to have a Privacy Certificate approved by the NIJ Human Subjects Protection Officer.
2. All Researchers and Research Staff are required to sign Employee Confidentiality Statements, which are maintained by the responsible Researcher.
3. The confidentiality statement on the consent form must state that confidentiality can only be broken if the subject reports immediate harm to subjects or others.
4. Under a privacy certificate, Researchers and Research Staff do not have to report child abuse unless the subject signs another consent form to allow child abuse reporting.
5. 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.