UNIVERSITY OF SOUTHERN MAINE
Office of Research Integrity & Outreach

Procedure #:	HRPP-049
AAHRPP	Element I.1.A., Element I.1.D., Element I.1.F., Element II.3.C., Element II.3.E., Element II.3.F., Element III.1.C., Element III.2.B., & Element III.2.D.
Date Adopted:	
Last Updated:	
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Updated By:	
Reviewed By:	
Procedure Title:	Research Supported by Department of Justice

1.0 Objective

1.1. To describe the primary ethical and legal principles applied to human subject research covered by the University of Southern Maine (USM) Human Research Protection Program (HRPP).

2.0 General Description

2.1. Research conducted within the Bureau of Prisons: Implementation of Bureau programmatic or operational initiatives made through pilot projects is not considered to be research.

2.2. Research conducted within the Bureau of Prisons, USM IRB, Principal Investigators, and research staff must follow the requirements of 28 CFR 512, including:

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

2.2.2. The research design must be compatible with both the operation of prison facilities and protection of human participants. The Investigator must observe the rules of the institution or office in which the research is conducted;

2.2.3. 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;

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

2.3. 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. Related to HRPP-028 IRB Reliance.

3.0 Definitions

3.1. **Privacy Certificate** assures that the applicant understands their responsibilities to protect the confidentiality of research and statistical information and has developed specific procedures to ensure that the information is only used or revealed in accordance with the requirements of 34 U.S.C. § 10231a and 28 CFR Part 22. Applicants for National Institute of Justice (NIJ) funding must submit a Privacy Certificate.

3.1. **Department of Justice (DOJ) Research** applies to research conducted, supported, or otherwise subject to regulation by the DOJ (or one of its agencies), which is usually carried out through the National Institute of Justice (NIJ).

4.0 Responsibility

4.1. It is the responsibility of the ORIO staff, Research Compliance Administrator (RCA), Institutional Review Board (IRB), and Principal Investigators to execute this SOP.

4.2. For research conducted within the Bureau of Prisons, the Principal Investigator must assume responsibility for actions of any person engaged to participate in the research project as an associate, assistant, or subcontractor to the Investigator.

4.3. It is the responsibility of the Principal Investigator to ensure compliance with any additional National Institute of Justice (NIJ) requirements for human subject protection. It is also the responsibility of the IRB to ensure that additional requirements for human subject protection have been met prior to IRB approval of the research project. Including, but not limited to additional educational training.

4.4. There are no additional training requirements for DOJ studies. Researchers and their study staff are expected to take human participants research training as required by USM, and maintain this certification while participating in a DOJ trial. USM uses the CITI program for this training. The NIH has a FAQ that discusses who on the researcher's study team is required to have human participants training, and what programs satisfy this requirement.

4.5. Principal Investigators must reflect all Department of Justice (DOJ), and National Institute of Justice (NIJ) requirements in their IRB application prior to approval.

5.0 Procedure

5.1. Evaluation of the equitable selection of participants

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

5.1.2. 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.

5.1.3. Reasonable accommodations such as nominal monetary recompense for time and effort may be offered to non- confined research participants who are both:

5.1.3.1. No longer in Bureau of Prisons custody;
5.1.3.2. Participating in authorized research being conducted by Bureau employees or contractors.

5.2. For National Institute of Justice (NIJ) funded research:

5.2.1. All projects are required to have a Privacy Certificate approved by the NIJ Human Subjects Protection Officer regardless of whether the project involves the collection of identifiable data.

5.2.1.1. In projects where no personally identifiable information will be collected, the Privacy Certificate should state in writing that it was approved by the NIJ Human Subjects Protection Officer and provide a brief project description.
5.2.1.2. Submission of a Privacy Certificate is required for IRB approval and must be submitted with the IRB application.
5.2.1.3. The Principal Investigator is responsible for submitting the completed Privacy Certificate to NIJ.
5.2.1.4. To obtain a Privacy Certificate or to find further instructions and guidelines, Principal Investigators should visit the Privacy Certificate guidance on the NIJ Website.

5.2.2. All researchers and research staff are required to sign employee confidentiality statements, which are maintained by the responsible researcher.

5.2.3. For National Institute of Justice (NIJ)-funded research, the consent document must disclose the name(s) of the funding agency(ies).

5.2.4. For National Institute of Justice-funded research, 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.

5.2.4.1. At least once a year, the Principal Investigator shall provide the Chief, Office of Research and Evaluation, with a report on the progress of the research.
5.2.4.2. At least 12 working days before any report of findings is to be released, the Principal 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 Principal Investigator shall include an abstract in the report of findings.

5.2.4.3. In any publication of results, the Principal Investigator shall acknowledge the Bureau's participation in the research project.

5.2.4.4. The Principal Investigator shall expressly disclaim approval or endorsement of the published material as an expression of the policies or views of the Bureau.

5.2.4.5. Prior to submitting for publication the results of a research project conducted under this subpart, the Principal 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.

5.3. For research conducted with the Bureau of Prisons:

5.3.1. A non-employee of the Bureau may receive records in a form not individually identifiable when advance adequate written assurance that the record will be used solely as statistical research or reporting record is provided to the agency.

5.3.2. Except as noted in the consent statement to the participant, the Principal Investigator must not provide research information that identifies a participant to any person without that participant'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 pertain.

5.3.3. Except for computerized data records maintained at an official Department of Justice (DoJ) site, records that contain non-disclosable information directly traceable to a specific person may not be stored in, or introduced into, an electronic retrieval system.

5.3.4. If the Principal Investigator is conducting a study of special interest to the Office of Research and Evaluation (ORE) but the study is not a joint project involving ORE, the Principal Investigator may be asked to provide ORE with the computerized research data, not identifiable to individual participants, accompanied by detailed documentation. These arrangements must be negotiated prior to the beginning of the data collection phase of the project.

5.3.5. The consent document must disclose:

5.3.5.1. The identity of all researchers.

5.3.5.2. Anticipated uses of the results of the research.

5.3.5.3. The extent to which confidentiality of records identifying the participant will be maintained. For studies sponsored by NIJ, the participant should

be informed that private, identifiable information will be kept confidential and will only be used for research and statistical purposes. If, due to sample size or some unique feature, the identity of the individual cannot be maintained, the participants need to be explicitly notified. If the researcher(s) intends to disclose any information, the participant needs to be explicitly informed what information would be disclosed, under what circumstances, and to whom. The participant must be informed of any risks that might result from this disclosure and must explicitly provide written consent prior to participating in the research.

5.3.5.4. A statement that participation is completely voluntary and that the participant may withdraw consent and end participation in the project at any time without penalty or prejudice (the inmate will be returned to regular assignment or activity by staff as soon as practicable).

5.3.5.4.1. For example, a researcher may not guarantee confidentiality when the participant indicates intent to commit future criminal conduct or harm himself or herself or someone else, or, if the participant is an inmate, indicates intent to leave the facility without authorization.

5.3.5.5. A statement that participation in the research project will have no effect on the inmate participant's release date or parole eligibility.

5.3.6. For research conducted within the Bureau of Prisons, the researcher(s) must have academic preparation or experience in the area of study of the proposed research.

5.3.6.1. For research conducted within the Bureau of Prisons, when submitting a research proposal, the applicant shall provide the following information:

5.3.6.1.1. A summary statement, which includes:

5.3.6.1.1.1. Names and current affiliations of the researchers.

5.3.6.1.1.2. Title of the study.

5.3.6.1.1.3. Purpose of the study.

5.3.6.1.1.4. Location of the study.

5.3.6.1.1.5. Methods to be employed.

5.3.6.1.1.6. Anticipated results.

5.3.6.1.1.7. Duration of the study.

5.3.6.1.1.8. Number of participants (staff or inmates) required, and amount of time required from each.

5.3.6.1.1.9 Indication of risk or discomfort involved as a result of participation.

5.3.6.1.2. A comprehensive statement, which includes:

5.3.6.1.2.1. Review of related literature.

5.3.6.1.2.2. Detailed description of the research method.

5.3.6.1.2.3. Significance of anticipated results and their contribution to the advancement of knowledge.

5.3.6.1.2.4. Specific resources required from the Bureau of

Prisons.

5.3.6.1.2.5. Description of all possible risks, discomforts, and benefits to individual participants or a class of participants, and a discussion of the likelihood that the risks and discomforts will actually occur.

5.3.6.1.2.6. Description of steps taken to minimize any risks.

5.3.7. Description of physical or administrative procedures to be followed to:

5.3.7.1. Ensure the security of any individually identifiable data that are being collected for the study.

5.3.7.2. Destroy research records or remove individual identifiers from those records when the research has been completed.

5.3.8. Description of any anticipated effects of the research study on organizational programs and operations.

5.3.9. Relevant research materials such as vitae, endorsements, sample consent statements, questionnaires, and interview schedules.

5.3.10. A statement regarding assurances and certification required by 28 CFR 46, if applicable.

6.0 References

6.1. 28 CFR 512;

6.2. 28 CFR 46;

6.3. 28 CFR 22.