1. **Purpose**

   The purpose of this SOP is to establish written requirements to ensure compliance with U.S. Department of Justice requirements regarding human subjects research. This SOP specifies requirements for research supported by the National Institute of Justice (NIJ) and/or conducted within the Bureau of Prisons (BOP).

   General requirements for conducting DOJ-regulated research are set forth at 28 CFR 46. Research conducted within the Bureau of Prisons is subject to additional requirements set forth in 28 CFR 512.

2. **Responsibility**

   The UNC-Chapel Hill IRB and researchers conducting human subjects research supported by the Department of Justice are responsible for ensuring compliance with this SOP.

3. **Definitions**

   **Certification** means the official notification by the institution to the supporting department or agency, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

   **Human subject** means a living individual about whom an investigator (whether professional or student) conducting research obtains:

   (1) Data through intervention or interaction with the individual, or
   (2) Identifiable private information.

   **Intervention** includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. **Private information** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

   **Minimal risk** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
Research

For purposes of research conducted within the Bureau of Prisons only, implementation of Bureau of Prisons programmatic or operational initiatives made through pilot projects is not considered to be research.

4. Procedures

4.1 NIJ-Supported Research:

UNC-Chapel Hill researchers receiving support from the NIJ to conduct human subjects research are required to comply with Department of Justice regulations at 28 CFR 46. The Department of Justice is not a signatory to the 2018 Revised Common Rule. As such, note that all NIJ/BOP non-exempt research will require a continuing review.

UNC-Chapel Hill researchers are responsible for communicating with their NIJ Program Officer to ensure that all NIJ requirements are met prior to starting an IRB-approved study. NIJ requirements include:

- **Privacy Certificate**: All projects are required to have a privacy certificate approved by the NIJ human subjects protection officer.
- **Child Abuse Reporting**: Under a privacy certificate, researchers and research staff do not have to report child abuse unless the participant signs another consent document to allow child abuse reporting.
- **Employee Confidentiality Statements**: All researchers and research staff are required to sign employee confidentiality statements, which are maintained by the responsible researcher.
- **Confidentiality Statement in the Consent Form**: The confidentiality statement in the consent document must state that confidentiality can only be broken if the participant reports immediate harm to participants or others.
- **De-identified Data Sent to the National Archive**: 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.

4.2 Research Conducted within the Bureau of Prisons:

UNC-Chapel Hill researchers conducting research within the Bureau of Prisons (BOP) are required to comply with Bureau of Prisons regulations at 28 CFR 512.

UNC-Chapel Hill researchers are responsible for communicating with the BOP to ensure that all requirements are met prior to starting an IRB-approved study. BOP requirements include:

- In all research projects, the rights, health, and human dignity of individuals involved must be respected.
- The project must have an adequate research design and contribute to the advancement of knowledge about corrections.
- The project must not involve medical experimentation, cosmetic research, or pharmaceutical testing.
The project must minimize risk to subjects; risks to subjects must be reasonable in relation to anticipated benefits. The selection of subjects within any one institution must be equitable. When applicable, informed consent must be sought and documented (see 28 CFR 512.15 and 512.16).

Incentives may not be offered to help persuade inmate subjects to participate. However, soft drinks and snacks to be consumed at the test setting may be offered. Reasonable accommodations such as nominal monetary recompense for time and effort may be offered to non-confined research subjects who are both:
- No longer in Bureau of Prisons custody, and
- Participating in authorized research being conducted by Bureau employees or contractors.

The researcher must have academic preparation or experience in the area of study of the proposed research.

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

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.

The researcher must adhere to applicable provisions of the Privacy Act of 1974 and regulations pursuant to this Act.

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.

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

A non-employee of the Bureau of Prisons 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.

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

If the researcher 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 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 project.
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Previous Version Dates:

- The researcher must submit planned methodological changes in a research project to the IRB for approval and may be required to revise study procedures in accordance with the new methodology.
BOP Research Proposals: When submitting research proposals to conduct research within the BOP, UNC-Chapel Hill researchers must include the following within their proposals:

- A summary statement, which includes:
  - Name(s) and current affiliation(s) of the researcher(s);
  - Title of the study;
  - Purpose of the project;
  - Location of the project;
  - Methods to be employed;
  - Anticipated results;
  - Duration of the study;
  - Number of subjects (staff/inmates) required and amount of time required from each; and
  - Indication of risk or discomfort involved as a result of participation.

- A comprehensive statement, which includes:
  - Review of related literature;
  - Detailed description of the research method;
  - Significance of anticipated results and their contribution to the advancement of knowledge;
  - Specific resources required from the Bureau;
  - 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;
  - Description of steps taken to minimize any risks described in (b)(5) of this section.
  - Description of physical and/or administrative procedures to be followed to:
    - Ensure the security of any individually identifiable data that are being collected for the project, and
    - Destroy research records or remove individual identifiers from those records when the research has been completed.
  - Description of any anticipated effects of the research project on institutional programs and operations; and
  - Relevant research materials such as vitae, endorsements, sample informed consent statements, questionnaires, and interview schedules.

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

All research proposals involving BOP research must be reviewed by the BOP Research Review Board.

BOP Informed Consent Requirements: Before commencing a research project requiring participation by BOP staff or inmates, the researcher shall give each participant a written informed consent statement containing the following information:

- Identification of the principal investigator(s);
- Objectives of the research project;
- Procedures to be followed in the conduct of research;
- Purpose of each procedure;
- Anticipated uses of the results of the research;
- A statement of benefits reasonably to be expected;
- A declaration concerning discomfort and risk, including a description of anticipated discomfort and risk;
- 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);
- 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.
- A statement that participation in the research project will have no effect on the inmate participant’s release date or parole eligibility;
- An offer to answer questions about the research project;
- Appropriate additional information as needed to describe adequately the nature and risks of the research; and
- Researchers who are non-BOP employees, in addition to presenting the statement of informed consent to subjects, shall also obtain the subject’s signature on the statement of informed consent prior to initiating the research activity. The researcher may not be required to obtain the signature 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 signed statement shall be submitted to the chairperson of the appropriate local research review board.

**BOP Reporting Requirements:** UNC-Chapel Hill researchers conducting research within the BOP shall prepare reports of progress on the research and at least one report of findings.

- 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 (BRRB), the regional director, and the warden of each institution which provided data or assistance. The researcher shall include an abstract in the report of findings.

**Publishing BOP Research:** A researcher may publish in book form and professional journals the results of any research project conducted within the BOP in accordance with the following:
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- In any publication of results, the researcher shall acknowledge the Bureau's participation in the research project.
- The researcher shall expressly disclaim approval or endorsement of the published material as an expression of the policies or views of the Bureau.
- Prior to submitting for publication the results of a research project conducted within the BOP, the researcher shall provide two copies of the material, for informational purposes only, to the Chief, Office of Research and Evaluation, Central Office, Bureau of Prisons.