25.12 Research Supported by the Department of Justice (DOJ)

To ensure that human subjects are adequately protected from unreasonable risks and properly informed of the potential harms and benefits from their participation in research, the National Institute of Justice (NIJ) and recipients of its funds are required to comply with 28 CFR Part 46 (Protection of Human Subjects) or the "Common Rule."

All projects funded under NIJ are required to submit a NIJ Privacy Certificate. Submission of a Privacy Certificate as part of an IRB application is required regardless of whether the project involves the collection of identifiable data. In cases where no personally identifiable information will be collected, the Privacy Certificate should contain a statement to this effect and a brief project description. The Privacy Certificate assures that the applicant understands his responsibilities to protect the confidentiality of research and statistical information and has developed specific procedures to ensure that this information is only used or revealed in accordance with the requirements of 42 USC §3789g and 28 CFR Part 22. The Privacy Certificate is signed by the Principal Investigator(s), submitted with the IRB application, and is then signed by the IO upon successful completion of the IRB processes. The principal investigator is responsible for submitting the completed Privacy Certificate to NIJ. Privacy Certificate instructions and guidelines can be found at the NIJ website.

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

It is the responsibility of the principal investigator to ensure compliance with any additional NIJ requirements for human subject protection. It also is 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.

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

Additionally, for all research conducted within the Bureau of Prisons, UVA, the IRBs, and researchers and research staff must follow the requirements of 28 CFR 512, including:

- The project must not involve medical experimentation, cosmetic research, or pharmaceutical testing.
- 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 must sign a statement in which the researcher agrees to adhere to the provisions of 28 CFR 512.
- All research proposals will be reviewed by the Bureau Research Review Board.

Further considerations include:

- 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 a statistical research or reporting record is provided to the agency.
- Except as noted in the consent statement to the subject, the researcher must not provide research information that 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 pertain.
- Except for computerized data records maintained at an official 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.
- 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.

The research protocol submitted to the IRB must address the following:

- Research conducted within the Bureau of Prisons must have an adequate research design and contribute to the advancement of knowledge about corrections.
- The selection of subjects within any one organization must be equitable
- 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, research coordinator, sub investigator or subcontractor to the researcher.
- The researcher must include the following in the application to the IRB:
    - A summary statement, which includes:
        - Names and current affiliations of the researchers
        - Title , purpose and location of the study
        - Methods to be employed
        - Anticipated results
        - Duration of the study

        - Number of subjects (staff or inmates) required and amount of time required from each
        - 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 of Prisons
    - 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
    - Description of any anticipated effects of the research study on organizational programs and operations
    - Relevant research materials such as vitae, endorsements, sample consent statements, questionnaires, and interview schedules.
    - A statement regarding assurances and certification required by 28CFR46, if applicable.
- The following consent elements are required:
    - For National Institute of Justice (NIJ)-funded research the consent document must disclose:
        - The name(s) of the funding agency(ies).
    - For research conducted within the Bureau of Prisons required elements of disclosure include:
        - The identity of the researchers.
        - Anticipated uses of the results of the research.
        - The extent to which confidentiality of records identifying the subject will be maintained. For studies sponsored by NIJ, the subject 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 subjects need to be explicitly notified. If the researcher intends to disclose any information, the subject needs to be explicitly informed what information would be disclosed, under what circumstances, and to whom. The subject must be informed of any risks that might result from this disclosure and must explicitly provide written consent prior to participating in the research.
        - A statement that participation is completely voluntary and that the subject 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 intent to commit future criminal conduct or harm himself or herself or someone else, or, if the subject is an inmate, indicates intent to leave the facility without authorization.
- A statement that participation in the research project will have no effect on the inmate subject's release date or parole eligibility.

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.

- 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.
- 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 under this subpart, 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.