Issuing Department: Human Subjects Protection Program (HSPP)
Policy Number: 2014-033.0
Policy Title: Additional Requirements – Federal Bureau of Prisons

Purpose

The purpose of this policy is to set forth additional requirements that are applicable to research conducted within the Federal Bureau of Prisons.

Definitions

Policy

Although some research may be exempt from 28 CFR part 46 under §46.101(b)(5), as determined by the Office of Research and Evaluation (ORE) of the Bureau, no research is exempt from 28 CFR part 512, Subpart B.

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

Requirements for Research Projects and Researchers:
The following requirements must be met:

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.

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

- No longer in Bureau of Prisons custody.
- 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 consent statement to the participant, the Researcher 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.

The research design must be compatible with both the operation of prison facilities and protection of human participants. 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 requirements of 28 CFR 512, Subpart B. 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.

Except for computerized data records maintained at an official Department of Justice 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 participants, accompanied by detailed documentation. These arrangements must be negotiated prior to the beginning of the data collection phase of the project.

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.

Content of Research Proposal.

When submitting a research protocol, the applicant must provide the following information:

- A summary statement, which includes:
    - Names and current affiliations of the Researchers.
    - Title of the study.
    - Purpose of the study.
    - Location of the study.
    - Methods to be employed.
    - Anticipated results.
    - Duration of the study
    - Number of participants (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 participants or a class of participants, and a discussion of the likelihood that the risks and discomforts will actually occur.
        - Description of steps taken to minimize any risks.
    - Description of physical or administrative procedures to be followed to:
        - Ensure the security of any individually identifiable data that are being collected for the study.
        - Destroy research records or remove individual identifiers from those records when the research has been completed.

        - 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 federal regulations, if applicable.

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

Access to Bureau of Prison Records:

Employees, including consultants, of the Bureau who are conducting authorized research projects shall have access to those records relating to the subject which are necessary to the purpose of the research project without having to obtain the subject's consent

A non-employee of the Bureau is limited in access to information available under the Freedom of Information Act.

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.

Informed Consent.

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

- Identification of the Principal Investigator.
- Objectives of the research project
- Procedures to be followed in the conduct of the 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 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.
- 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

A researcher who is a non-employee of the Bureau, in addition to presenting the statement of informed consent to the subject, 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.

Reports:

At least once a year, the Researcher must 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 must 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 must include an abstract in the report of findings.

Publications:

A researcher may publish in book form and professional journals the results of any research project conducted under this subpart.

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 28 CFR 5112 Subpart B, the Researcher must provide two copies of the material, for informational purposes only, to the Chief, Office of Research and Evaluation, Central Office, Bureau of Prisons.

Procedure

Principal Investigator must review, sign and submit Appendix J to the IRB application.

Principal investigator must also submit form C, if prisoners within the Bureau are to be enrolled.

The IRB will then review the forms in accordance with standard review practices to ensure all required elements have been addressed.

Related Policies

2011-006.0 - Additional Protections: General Policy
2011-006.2 – Additional Protections: Prisoners
2011-009.3 - Institutional Review Board – Expedited Reviews
2011-009.5 – Institutional Review Board - Review by Convened Board
2011-009.12 – Institutional Review Board – Criteria for Approval

Basis

28 CFR 46 / 45 CFR 46
28 CFR 512, Subpart B

Document Attributes

Date Effective: 11/20/2023

Replaced Version: 6/14/2017

Reviewed and Approved By:

Richard H. Simon ***11/01/2023***
Richard Simon, MD **Date**
Director, Human Subjects Protection Program