UNLV | Office of RESEARCH INTEGRITY HUMAN SUBJECTS

Guidance – Department of Justice (DOJ) and Bureau of Prisons Requirements

General Description

Research that is regulated by federal agencies often times have agency-specific requirements. This guidance is to assist researchers and the IRB in identifying additional regulatory considerations.

28 CFR 512.10 Purpose and Scope

> General provisions for the protection of human subjects during the conduct of research are contained in 28 CFR part 46. The provisions of this subpart B specify additional requirements for prospective researchers (both employees and non-employees) to obtain approval to conduct research within the Bureau of Prisons (Bureau) and responsibilities of Bureau staff in processing proposals and monitoring research projects. 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. For the purpose of this subpart, implementation of Bureau programmatic or operational initiatives made through pilot projects is not considered to be research.

When it applies / context

This guidance may be used by members of the UNLV Human Research Protection Program (HRPP), Researchers and the IRB. Researchers should review this guidance when conducting research supported by the Department of Justice (DOJ) within the Bureau of Prisons. The IRB should use this guidance to review for agency-specific requirements in research supported by the DOJ.

Considerations & Best Practices

Bureau of Prisons

Considerations

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

For research conducted within the Bureau of Prisons, UNLV, the IRB, 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 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.

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

Best Practices

For research conducted within the Bureau of Prisons:

- The project must have an adequate research design and contribute to the advancement of knowledge about corrections.
- The selection of participants within any one organization must be equitable.
- 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.
- A non-employee of the Bureau may receive records in a form not individually identifiable when advance adequate written assurance is provided to the agency. The assurance should include a statement that the record will be used solely as a statistical research or reporting record.
- 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.
- 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 participants, accompanied by detailed documentation. *These arrangements must be negotiated prior to the beginning of the data collection phase of the project.*
- Required elements of written Informed Consent include:
    - Identification of the Researchers.
    - Anticipated uses of the results of the research.
    - 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.

- The Researcher must have academic preparation or experience in the area of study of the proposed research.
- When submitting a research protocol, the applicant must provide the following information:
    - 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.
    - 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.
- 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.
- For research conducted with the Bureau of Prisons:
    - 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.
    - In any publication of results, the Researcher must acknowledge the Bureau's participation in the research project.
    - The Researcher must 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 must provide two copies of the material, for informational

purposes only, to the Chief, Office of Research and Evaluation, Central Office, Bureau of Prisons.

Additional Requirements for National Institute of Justice (NIJ)-Funded Research

For National Institute of Justice (NIJ)-funded research:

- All projects are required to have a privacy certificate approved by the NIJ human subjects protection officer.
- All Researchers and Research Staff are required to sign employee confidentiality statements, which are maintained by the responsible Researcher.

- The written Informed Consent will include:
  - The name(s) of the funding agency(ies).
  - A statement describing 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 participants need to be explicitly notified. If the Researcher 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.

- 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.
- 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.

Resources

28 CFR 512

28 CFR 22

AAHRPP Elements I.1.A., I.1.D., I.1.F., II.3.C., II.3.E., II.3.F., III.1.C., III.2.B., III.2.D.