Guidance: Additional Requirements for Department of Justice (DOJ) Sponsored Research

1. Introduction

The DOJ has adopted the Common Rule at 28 CFR 46 and has also published additional requirements for research conducted with the Bureau of Prisons and for research involving the National Institute of Justice. Researchers must be aware of these additional requirements. The requirements outlined in this guidance do not apply to implementation of Bureau programmatic or operational initiatives made through pilot projects, as these projects are not considered to be research.

2. Research Conducted with the Bureau of Prisons

Research conducted with/in the Federal Bureau of Prisons is subject to the requirements of the Common Rule and for the protection of prisoners found in Subpart C. Additional unique regulatory requirements are outlined in 28 CFR 512 and included below.

2.1 Research Proposal and Design

a. The project must have an adequate research design and contribute to the advancement of knowledge about corrections.
b. The project must not involve medical experimentation, cosmetic research, or pharmaceutical testing.
c. 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.
d. When submitting a research protocol, the applicant must provide the following items. Please note: these items are required for the standard U-M IRB application and are not additional requirements for DOJ-funded studies.
  i. A summary statement, which includes:.
    1. Name(s) and current affiliation(s) of the researcher(s);
    2. Title of the study;
    3. Purpose of the study;
    4. Location of the study;
    5. Methods to be employed;
    6. Anticipated results;
    7. Duration of the study;
    8. Number of subjects (staff/inmates) required and amount of time required from each; and
    9. Indication of risk or discomfort involved as a result of participation
  ii. A comprehensive statement, which includes:
    1. Review of related literature;
    2. Detailed description of the research method;
    3. Significance of anticipated results and their contribution to the advancement of knowledge;
    4. Specific resources required from the Bureau;
    5. 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;

6. Description of steps taken to minimize any risks;
7. 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.
8. Description of any anticipated effects of the research project on institutional programs and operations; and
9. Relevant research materials such as vitae, endorsements, sample informed consent statements, questionnaires, and interview schedules.

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

2.2 Subject Selection and Incentives

a. The selection of participants with any organization must be equitable.

b. 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:

i. No longer in Bureau of Prisons custody; and

ii. Participating in authorized research being conducted by Bureau employees or contractors.

2.3 Investigator Requirements and Responsibilities

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

b. The 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.

c. Any investigator who is a non-employee of the Bureau must sign a statement in which the investigator agrees to adhere to the provisions of 28 CFR part 512 subpart B.

d. At least once a year, the investigator shall provide the Chief, Office of Research and Evaluation, with a report on the progress of the research.

e. At least 12 working days before any report of findings is to be released, the 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 investigator shall include an abstract in the report of findings.

f. A researcher may publish in book form and professional journals the results of any research project conducted under 28 CFR 512..

i. In any publication of results, the researcher shall acknowledge the Bureau's participation in the research project.

ii. The researcher shall expressly disclaim approval or endorsement of the published material as an expression of the policies or views of the Bureau.

g. Prior to submitting for publication the results of a research project conducted under 28 CFR 512, 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.

h. As a precondition to the conduct of research, a non-employee shall grant in writing to the

Bureau a royalty-free, non-exclusive, and irrevocable license to reproduce, publish, translate, and otherwise use and authorize others to publish and use original materials developed as a result of research conducted under this subpart.

2.4 Confidentiality, Privacy, and Access to Records

- **a.** Except as noted in the consent statement to the subject, the investigator 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 pertains.
- **b.** The researcher must adhere to applicable provisions of the Privacy Act of 1974 and regulations.
- **c.** 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.
- **d.** A non-employee of the Bureau is limited in access to information available under the Freedom of Information Act. However, 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.
- **e.** If the 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 investigator 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.

2.5 Informed Consent

- **a.** The written informed consent document must contain the following elements (in addition to the standard elements required by the Common Rule):
  - **i.** Identification of the principal investigator;
  - **ii.** Anticipated uses of the results of the research;
  - **iii.** A statement that participation is voluntary and that the subject can withdraw consent at any time without penalty or prejudice (and will be returned to regular assignment or activity by staff as soon as practicable);
  - **iv.** A statement regarding the confidentiality of 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/herself or someone else, or, if the subject is an inmate, indicates intent to leave the facility without authorization.);
  - **v.** A statement that participation in the research project will have no effect on the inmate participant's release date or parole eligibility.
- **b.** Signed (documented) informed consent is required for research conducted by a researcher who is a non-employee of the Bureau. A waiver of documentation of informed consent can be approved 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.

3. Research involving the National Institute of Justice (NIJ)

In addition to Common Rule requirements, research projects involving the NIJ must meet the requirements of 28 CFR 22 – Confidentiality of Identifiable Research and Statistical Information (CIPSEA). Researchers are responsible for consulting with their NIJ Program Officer to confirm that all NIJ requirements are met prior to beginning research. Among those requirements are the following:

a. A Privacy Certificate must be approved by the NIJ Human Subjects Protection Officer, see NIJ Privacy Certificate Guidance;

b. All investigators and research staff are required to sign Employee Confidentiality Statements, which are maintained by the responsible investigator;

c. Informed Consent
The informed consent document must include the following information:

- The name of the funding agency;
- A statement describing confidentiality of subject records
  - The subject must 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 and the identity of the individual cannot be protected, the subject must be explicitly notified;
  - If the investigator 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;
  - Researchers are not required to report child abuse unless the subject signs another consent document to allow child abuse reporting.

d. A copy of all data must be de-identified and sent to the National Archive of Criminal Justice, including copies of the informed consent document, data collection instruments, surveys, or other relevant research materials. See NIJ Guidance for Applicants and Awardees.

References

Bureau of Prisons – 28 CFR 512

National Institute of Justice – 28 CFR 46

Additional Guidance:

- NIJ Confidentiality and Privacy Protections
- NIJ Human Subjects Protection
- NIJ Guidance for Applicants and Awardees

Confidentiality of Identifiable Research and Statistical Information (CIPSEA) – 28 CFR 22