

# OFFICE FOR EDUCATION & QUALITY IN CLINICAL RESEARCH

## GUIDANCE #2

### Additional Requirements for Research Involving the Department of Justice (DOJ)

#### 1. Overview

This guidance is for investigators and staff involved with research involving the Department of Justice (DOJ) and the National Institute of Justice (NIJ).

#### 2. Applicable Regulations and Guidelines

28 CFR 22

28 CFR 46

28 FR 512

#### 3. For Research Conducted Within the Bureau of Prisons

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

B. The organization, the OHSR (HSRC and CRC), researchers and research staff must follow the requirements of 28 CFR 512.

- i. The project must not involve medical experimentation, cosmetic research, or pharmaceutical testing.
- ii. 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.
- iii. The researcher must assume responsibility for actions of any persons engaged to participate in the research project as an associate, assistant, or subcontractor to the researcher.
- iv. 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.
- v. The Bureau Research Review Board will review all research proposals and monitor research projects at least yearly.

C. Review of Research

- i. The researcher must have academic preparation or experience in the area of study of the proposed study.
- ii. Investigators submit preliminary research proposals for review by the Bureau of Prisons Office of Research and Evaluation. If the study is to be conducted at only one institution, the applicant submits a formal proposal to the warden of that institution. If the study is to be conducted at more than one institution or at any other Bureau location, the applicant submits the research proposal to the Chief, Office of Research and Evaluation.
- iii. When submitting a research proposal, provide the following information:
  - a. A summary statement, which includes:
    - 1) Names and current affiliations of the researchers
    - 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 participants (staff or inmates) required and amount of time required from each
- 9) Indication of risk or discomfort involved as a result of participation
- b. 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 of Prisons
  - 5) Description of all possible risks, discomforts, and benefits to individual participants or a class of participants; discussion of the likelihood that the risks and discomforts will actually occur; description of the steps taken to minimize risks
  - 6) Description of physical or administrative procedures to be followed to:
    - a) Ensure the security of any individually identifiable data that are being collected for the study
    - b) Destroy research records or remove individual identifiers from those records when the research has been completed
  - 7) Description of any anticipated effects of the research study on organizational programs and operations
  - 8) Relevant research materials such as vitae, endorsements, sample consent statements, questionnaires, and interview schedules
- c. A statement regarding assurances and certification required by federal regulations, if applicable
- iv. The project must have an adequate research design and contribute to the advancement of knowledge about corrections.
- v. The selection of participants within any one organization must be equitable.
- vi. 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.
- vii. Reasonable accommodations such as nominal monetary recompense for time and effort may be offered to non-confined research participants who are both:
  - a. No longer in Bureau of Prisons custody
  - b. Participating in authorized research being conducted by Bureau employees or contractors
- viii. 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.
- ix. 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.
- x. 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.

- xi. 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.
- xii. Required elements of consent include the following:
  - a. Identification of the researchers
  - b. Anticipated uses of the results of the research
  - c. A statement that participation is completely voluntary and 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)
  - d. 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
  - e. A statement that participation in the research project will have no effect on the inmate participant's release date or parole eligibility

**D. Reporting Requirements**

- i. 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.
- ii. 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.
- iii. In any publication of results, the Researcher shall acknowledge the Bureau's participation in the research project.
- iv. The Researcher shall expressly disclaim approval or endorsement of the published material as an expression of the policies or views of the Bureau.
- v. 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.

**3. For Research Funded by the National Institute of Justice**

- A.** All projects are required to have a privacy certificate approved by the NIJ human subjects protection officer. For more information see the Model Privacy Certificate at <http://www.nij.gov/nij/funding/humansubjects/model-privacy-certificate.htm>
- B.** 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.
- C.** All researchers and research staff are required to sign employee confidentiality statements, which must be maintained by the responsible researcher.
- D.** The confidentiality statement on the consent document must state that confidentiality can only be broken if the participant reports immediate harm to participants or others.

- E.** 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. Submission and Reporting**

Reporting must be completed as required in the terms and conditions of the funding agency award document and in accordance with award management procedures.
- 5. Investigator Resources**
  - A.** Because of the uniqueness of DOJ research and numerous requirements (including the aforementioned reporting requirements), an Investigator must work closely with the Office for Human Subjects Research and the Office of Grants & Contracts.
  - B.** Early collaboration with the appropriate Grant Administrator and the OHSR is essential when planning DOJ research.