

INVESTIGATOR GUIDANCE: Additional DOJ Obligations

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1. PURPOSE

- 1.1. This guidance outlines the additional obligations of investigators conducting research supported or conducted by DOJ.

2. GUIDANCE

2.1. National Institute of Justice (NIJ)-funded research

- 2.1.1. Investigators must have a privacy certificate approved by the NIJ human subjects protection officer.
- 2.1.2. Investigators and research staff must sign employee confidentiality statements, and investigators must maintain these statements.
- 2.1.3. Investigators must obtain written informed consent and disclose
 - 2.1.3.1. The names of the funding agencies.
 - 2.1.3.2. The extent to which confidentiality of records identifying the subject will be maintained.
 - 2.1.3.3. Private, identifiable information will be kept confidential and will only be used for research and statistical purposes.
 - 2.1.3.3.1. 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 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.

2.2. Research conducted within the Bureau of Prisons

- 2.2.1. The Department of Justice does not consider implementation of Bureau of Prisons programmatic or operational initiatives made through pilot projects to be research.
- 2.2.2. Investigators must follow the requirements of 28 CFR 512
- 2.2.3. The research must not involve medical experimentation, cosmetic research, or pharmaceutical testing.
- 2.2.4. The research design must be compatible with both the operation of prison facilities and protection of human subjects.
- 2.2.5. The investigator must observe the rules of the institution or office in which the research is conducted.
- 2.2.6. The Bureau of Prisons Research Review Board must approve the research.
- 2.2.7. The research must have an adequate research design and contribute to the advancement of knowledge about corrections.
- 2.2.8. The selection of subjects within any one organization must be equitable.
- 2.2.9. Incentives may not be offered to help persuade inmate subjects to participate. Soft drinks and snacks to be consumed at the test setting may be offered.
- 2.2.10. Reasonable accommodations such as nominal monetary recompense for time and effort may be offered to non-confined research subjects who are both:
 - 2.2.10.1. No longer in Bureau of Prisons custody
 - 2.2.10.2. Participating in authorized research being conducted by Bureau of Prisons employees or contractors

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- 2.2.11. 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 pertain.
- 2.2.12. 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.
- 2.2.13. 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 research 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 research.
- 2.2.14. Consent documents must disclose:
- 2.2.14.1. Identification of the principal investigator(s).
 - 2.2.14.2. Objectives of the research project
 - 2.2.14.3. Procedures to be followed in the conduct of research
 - 2.2.14.4. Purpose of each procedure
 - 2.2.14.5. Anticipated uses of the results of the research
 - 2.2.14.6. A statement of benefits reasonably to be expected
 - 2.2.14.7. A declaration concerning discomfort and risk, including a description of anticipated discomfort and risk
 - 2.2.14.8. 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)
 - 2.2.14.9. A statement regarding the confidentiality of the research information and exceptions to any guarantees of confidentiality required by federal or state law. For example, an investigator may not guarantee confidentiality when the subject indicates an intent to commit future criminal conduct or harm himself/herself or someone else, or, if the subject is an inmate, indicates an intent to leave the facility without authorization.
 - 2.2.14.10. A statement that participation in the research project will have no effect on the inmate participant's release date or parole eligibility
 - 2.2.14.11. An offer to answer questions about the research project and
 - 2.2.14.12. Appropriate additional information as needed to describe adequately the nature and risks of the research
- 2.2.15. If the investigator is an employee of the Bureau of Prisons:
- 2.2.15.1. The consent statement must include a declaration of the authority under which the research is conducted.
 - 2.2.15.2. An investigator must obtain the subject's signature on the statement of informed consent, when:
 - 2.2.15.2.1. The subject's activity requires something other than response to a questionnaire or interview; or
 - 2.2.15.2.2. The Chief, ORE, determines the research project or data-collection instrument is of a sensitive nature.

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- 2.2.16. If the investigator is NOT an employee of the Bureau of Prisons:
- 2.2.16.1. The investigator must sign a statement in which the investigator agrees to adhere to the requirements of 28 CFR 512.
 - 2.2.16.2. The investigator 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.
 - 2.2.16.3. Must present the statement of informed consent to the subject.
 - 2.2.16.4. Must obtain the subject's signature on the statement of informed consent prior to initiating the research activity.
 - 2.2.16.4.1. The investigator may not be required to obtain the signature if the investigator 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.
- 2.2.17. Investigators must have academic preparation or experience in the area of study of the proposed research.
- 2.2.18. When submitting a research protocol, investigators must provide the following information:
- 2.2.18.1. A summary statement, which includes:
 - 2.2.18.1.1. Names and current affiliations of the investigators.
 - 2.2.18.1.2. Title of the study.
 - 2.2.18.1.3. Purpose of the study.
 - 2.2.18.1.4. Location of the study.
 - 2.2.18.1.5. Methods to be employed.
 - 2.2.18.1.6. Anticipated results.
 - 2.2.18.1.7. Duration of the study.
 - 2.2.18.1.8. Number of subjects (staff or inmates) required and amount of time required from each.
 - 2.2.18.1.9. Indication of risk or discomfort involved as a result of participation.
 - 2.2.18.2. A comprehensive statement, which includes:
 - 2.2.18.2.1. Review of related literature.
 - 2.2.18.2.2. Detailed description of the research method.
 - 2.2.18.2.3. Significance of anticipated results and their contribution to the advancement of knowledge.
 - 2.2.18.2.4. Specific resources required from the Bureau of Prisons.
 - 2.2.18.2.5. 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.
 - 2.2.18.2.5.1. Description of steps taken to minimize any risks.
 - 2.2.18.2.6. Description of physical or administrative procedures to be followed to:
 - 2.2.18.2.6.1. Ensure the security of any individually identifiable data that are being collected for the study.
 - 2.2.18.2.6.2. Destroy research records or remove individual identifiers from those records when the research has been completed.

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- 2.2.18.2.7. Description of any anticipated effects of the research study on organizational programs and operations.
- 2.2.18.2.8. Relevant research materials such as vitae, endorsements, sample consent statements, questionnaires, and interview schedules.
- 2.2.18.2.9. A statement regarding assurances and certification required by federal regulations, if applicable.
- 2.2.19. Investigators must assume responsibility for actions of any person engaged to participate in the research as an associate, assistant, or subcontractor to the investigator.
- 2.2.20. At least once a year, investigators must provide the Chief, Office of Research and Evaluation, with a report on the progress of the research.
- 2.2.21. At least 12 working days before any report of findings is to be released, investigators must distribute one copy of the report with an abstract in the report of findings to each of the following:
 - 2.2.21.1. The chairperson of the Bureau Research Review Board
 - 2.2.21.2. The regional director
 - 2.2.21.3. The warden of each institution that provided data or assistance
- 2.2.22. In any publication of results, investigators must acknowledge the Bureau's participation in the research.
- 2.2.23. Investigators expressly disclaim approval or endorsement of the published material as an expression of the policies or views of the Bureau.
- 2.2.24. Prior to submitting for publication the results of research conducted under this subpart, investigators must provide two copies of the material, for informational purposes only, to the Chief, Office of Research and Evaluation, Central Office, Bureau of Prisons.

3. REFERENCES

- 3.1. 28 CFR §22,
- 3.2. 28 CFR §512