

Summary of Department of Justice (DOJ), National Institute of Justice (NIJ), and Bureau of Prisons Human Research Requirements

Human research which is supported by the National Institute of Justice (NIJ) is governed by the Department of Justice (DOJ) regulations for the protection of human subjects ([28 CFR 46](#)) and the DOJ Confidentiality of Identifiable Research and Statistical Information regulations ([28 CFR 22](#)). Of the many [DOJ agencies](#), the NIJ has a primary mission to advance scientific research.

In addition, research conducted within the federal Bureau of Prisons (BoP) is subject to additional requirements set forth in [28 CFR 512](#).

In addition to this summary guidance, an IRB Checklist is available for use by the IRB in conducting review of DOJ regulated research.

Investigator requirements for research funded by NIJ:

Confidentiality Statements:

- All researchers and research staff are required to sign [employee confidentiality statements](#) as a condition of grant or proposal approval by the NIJ. Certificates are maintained by the responsible Research Investigator.

Privacy Certificates:

- All NIJ funded projects are required to have a Privacy Certificate approved by the NIJ human subjects' protection officer. The Privacy Certificate is the grant applicant's assurance that he/she understands his/her responsibilities to protect the confidentiality of research and statistical information. In cases where no personally identifiable information will be collected, the Privacy Certificate contains a statement to this effect and a brief project description. Investigators should refer to the NIJ Privacy Certificate Guidance and Model Privacy Certificate at <http://www.nij.gov/nij/funding/humansubjects/privacy-certificate-guidance.htm> for information that must be included, sample format, and instructions to avoid common problems. Note: The NIJ only accepts the Privacy Certificate. It does not issue or accept Certificate of Confidentiality issued by the National Institutes of Health (NIH).
- Under a Privacy Certificate, researchers and research staff do not have to report current or past abuse. Since this is in conflict with Kentucky child and elder abuse reporting laws, the investigator is obligated to such reporting, and therefore must make available a second consent (addendum) to allow such reporting, should a subject self-disclose or give staff strong reasons to believe the subject may be in a dangerous situation. A sample separate consent form (addendum) for reporting is available at <http://www.nij.gov/nij/funding/humansubjects/sample-form-consent-for-reporting.doc.doc>
- If data collection methodology and/or information provided in the privacy certificate changes due to Institutional Review Board (IRB) requirements, a revised privacy certificate must be provided prior to the commencement of research.

Consent requirements

- The consent must include 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. However, disclosure of future criminal intent is not covered or protected by DOJ regulations.
- If, due to sample size or some unique feature, the identity of the individual cannot be maintained, the subjects need to be explicitly notified. If the investigator intends to disclose any information, the subject needs to be explicitly informed what information would be disclosed, under what circumstances, and to whom. The subject must be informed of any potential risks which may result from this disclosure and must explicitly provide prior written consent.
- Subjects must be informed that study is funded by NIJ.

28 CFR 46.117 allows for waiver of documentation of informed consent when criteria are met.

Archiving:

- At the end of the award period, recipients of NIJ funding follow [guidelines](#) to submit data resulting from their projects to NIJ for archiving with the National Archive of Criminal Justice Data (NACJD), including copies of the informed consent document, data collection instruments, surveys, or other relevant research materials.

For additional guidance, refer to the frequently asked questions available at the NIJ FAQ website at <http://www.nij.gov/funding/humansubjects/faqs.htm>.

Requirements for research conducted within the Bureau of Prisons (BOP) [[28 CFR 512](#)]:

Regional BOP facilities are identified on the Federal BOP website- www.bop.gov/locations/maps/MXR.jsp

Federal Bureau of Prisons Research Proposals:

- Investigators submit preliminary research proposal for review by the BOP 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,
- When submitting a research proposal to the BOP Office of Research and Evaluation the researcher applicant provides 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 due to 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, and
 - 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.

Bureau Research Review Board:

- All research proposals must be reviewed by the Bureau Research Review Board (BRRB). The BRRB monitors research projects at least yearly, for compliance with Bureau policies. It is the investigator's responsibility to communicate and submit proposals to the BRRB.
- Implementation of Bureau programmatic or operational initiatives made through pilot projects is not considered by the Bureau to be research.
- A non-employee of the Bureau is limited in access to information available under the Freedom of Information Act. He/she 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:

- For research conducted within **the Bureau of Prisons**, additional required elements of **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.

Additional requirements for researchers based on 28 CFR 512:

- 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.
- 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; and
 - Participating in authorized research being conducted by Bureau employees or contractors.
- Except as noted in the informed consent document presented 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 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 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.
- 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.
- 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.

- 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 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.

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