

**University of Cincinnati Human Research Protection Program
Checklist for Department of Justice & Bureau of Prisons Research**

Principal Investigator:	
IRB Study #:	
Study Title:	
NOTE:	This checklist is intended to help you ensure that all human research requirements are addressed when your study is under the purview of the Department of Justice (DoJ) and the research is conducted within the Bureau of Prisons (BOP). Research initiated or funded by the DoJ and the BOP must be reviewed under an additional set of federal regulations (28 CFR Part 46 and 28 CFR Part 512) and applicable requirements must be met before study activities begin. The DoJ follows DHHS and FDA regulations for human subjects' research.

1. Pilot Project

The project conducted within the Bureau of Prisons and intended to implement a Bureau programmatic or operation initiative made through a pilot project?

Yes NO N/A

If “yes”, the pilot project is not considered human subjects research by the BOP and is not subject to BOP regulations per 28 CFR Part 512. Do not complete the remainder of the form.

2. Research Requirements

- The investigator and research staff are aware of and have educated themselves about the specific requirements of Department of Justice (DoJ) research with the Federal Bureau of Prisons (BOP)
- The project does not involve medical experimentation, cosmetic research or pharmaceutical testing
- The research design is compatible with both the operation of prison facilities and protection of human subjects
- The investigator will observe the rules of the institution or office in which the research is conducted
- Investigators, who are BOP employees, have signed a statement agreeing to adhere to the requirements of 28 CFR 512
- All research proposals will be reviewed by the BOP IRB

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- The project has an adequate design and will contribute to the advancement of knowledge about corrections

3. Investigator Responsibilities and Requirements

- The investigator has academic preparation or experience in the area of study of the proposed research
- The investigator will 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 investigator will 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 investigator will distribute one copy of the report to each of the following
 - a. the chairperson of the BOP IRB
 - b. the regional director
 - c. the warden of each institution that provided data or assistance
- The investigator will include an abstract in the report of findings
- If any publication of results, the investigator shall acknowledge the BOP's participation in the research project
- The investigator will expressly disclaim approval or endorsement of the published material as an expression of the policies or views of the BOP
- Prior to submitting for publication the results of a research project conducted under this subpart, the investigator shall provide two copies of the material, for informational purposes only, to the Chief, Office of Research and Evaluation, Ventral Office, BOP.

For research conducted within the Bureau of Prisons, when submitting a research proposal, the applicant shall provide the following information:

- A summary statement, which includes names and current affiliations of researchers, title of the study, purpose of the study, location of the study, methods to be employed, anticipates results, duration of the study, number of participants (staff or inmates) requires and amount of time required from each as well as indication of risk or discomfort involved as a result of participation.
- A comprehensive statement, which includes review of related literature, detailed description of the research method, significance of anticipates results and their contribution to the advancement of knowledge, specific resources requires from the Bureau of Prisons, a description of all possible risks, discomforts, and benefits to individual participants or a class of participants, and a discussion of the

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likelihood that the risks and discomforts will actually occur as well as a 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 28 CFR 46, if applicable.

For National Institute of Justice-funded research, 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.

For research conducted with the Bureau of Prisons:

- 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.

4. Confidentiality Requirements

For National Institute of Justice (NIJ) funded research:

- A privacy certificate approved by the NIJ Human Subjects Protection Officer will be obtained
- All researchers and research staff will sign an employee confidentiality statement and each form will be maintained by the responsible researcher

For research conducted with the Bureau of Prisons:

- A non-employee of the BOP will receive records in a form not individually identifiable, and advance adequate written assurance that the record will be used solely as a statistical research or reporting record

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has been provided to the agency

- Except as noted in the consent statement to the subject, the investigator will 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.
- 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 will not be stored in, or introduced to, an electronic retrieval system.
- 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. Researcher may be asked to provide ORE with the computerized research data, not identifiable to individual participants, accompanied by detailed documentation. These arrangements will be negotiated prior to the beginning of the data collection phase of the project