Overview

DOJ regulations (28 CFR. Part 46, “Protection of Human Subjects”) protect the human subjects of federally-funded research. The regulations require that, unless an exemption applies, OJP-funded research projects that involve human subjects must be reviewed and approved by an Institutional Review Board (IRB). Before a recipient will be permitted to use OJP funds for any research activity involving human subjects, the recipient must submit to OJP documentation of IRB approval that is sufficient to demonstrate compliance with the requirements of 28 CFR Part 46.

OJP has developed a decision tree to assist OJP applicants and recipients in determining whether an activity planned to be undertaken with OJP funds constitutes research involving human subjects. https://ojp.gov/funding/aplly/resources/researchdecisiontree.pdf.

Data Privacy and Confidentiality Requirements

DOJ regulations (28 CFR Part 22), “Confidentiality of Identifiable Research and Statistical Information”) require recipients, and any subrecipients under an OJP award, to protect the privacy of individuals by requiring that information identifiable to a private person obtained during an OJP-funded research or statistical program may only be used for the purpose for which the information was obtained.

Applicants that propose to conduct a research or a statistical project that will collect personally identifiable information must submit an acceptable “Privacy Certificate” as part of the application. The Privacy Certificate must include a complete description of the policies and procedures that the applicant will use to ensure the confidentiality of identifiable data. The eight elements required for a Privacy Certificate are outlined at 22 CFR 22.23.

A model Privacy Certificate can be found here: https://www.justice.gov/atr/file/705856/download

Additional Submission Requirements

1. Implementation of Bureau programmatic or operational initiatives made through pilot projects is not considered to be research.
2. The project must not involve medical experimentation, cosmetic research, or pharmaceutical testing.
3. The research design must be compatible with both the operation of prison facilities and protection of human subjects.
4. Investigators must observe the rules of the institution or office in which the research is conducted.
5. Any investigator who is a non-employee of the Bureau of Prisoners must sign a statement in which the investigator agrees to adhere to the requirements of 28 CFR §512.
6. The research must be reviewed and approved by the Bureau Research Review Board.
7. Incentives cannot 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: No longer in Bureau of Prisons custody. Participating in authorized research being conducted by Bureau employees or contractors.

8. 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.

9. Except as noted in the consent statement to the subject, you 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.

10. 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.

11. If you are conducting a study of special interest to the Office of Research and Evaluation but the study is not a joint project involving Office of Research and Evaluation, you may be asked to provide Office of Research and Evaluation 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.

12. Required elements of disclosure additionally include:
   a. Identification of the investigators.
   b. Anticipated uses of the results of the research.
   c. A statement that participation is completely voluntary and that the subject 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, an investigator may not guarantee confidentiality when the subject indicates intent to commit future criminal conduct or harm himself or herself or someone else, or, if the subject 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 subject’s release date or parole eligibility.

13. Researchers must have academic preparation or experience in the area of study of the proposed research.

14. The IRB application must include a summary statement, which includes:
   a. Names and current affiliations of the investigators.
   b. Title of the study.
   c. Purpose of the study.
   d. Location of the study.
   e. Methods to be employed.
   f. Anticipated results.
   g. Duration of the study.
   h. Number of subjects (staff or inmates) required and amount of time required from each.
   i. Indication of risk or discomfort involved as a result of participation.

15. The IRB application must include a comprehensive statement, which includes:
   b. Detailed description of the research method.
   c. Significance of anticipated results and their contribution to the advancement of knowledge.
   d. Specific resources required from the Bureau of Prisons.
   e. 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.
   f. Description of steps taken to minimize any risks.
   g. 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.
h. Destroy research records or remove individual identifiers from those records when the research has been completed.
i. Description of any anticipated effects of the research study on organizational programs and operations.
j. Relevant research materials such as vitae, endorsements, sample consent statements, questionnaires, and interview schedules.

16. The IRB application must include a statement regarding assurances and certification required by federal regulations, if applicable.

17. You must assume responsibility for actions of any person engaged to participate in the research project as an associate, assistant, or subcontractor.

18. At least once a year, a report must be provided to the Chief, Office of Research and Evaluation, on the progress of the research.

19. At least 12 working days before any report of findings is to be released, one copy of the report must be distributed 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.

20. An abstract in the report must be included of the findings.

21. The Bureau's participation in the research project must be acknowledged in any publication.

22. Researchers must disclaim approval or endorsement of the Bureau in any published material as an expression of the policies or views of the Bureau.

23. Prior to submitting for publication the results of a research project conducted under this subpart, the Researcher must provide two copies of the material, for informational purposes only, to the Chief, Office of Research and Evaluation, Central Office, Bureau of Prisons.

24. Other specific requirements of the Department of Justice (DOJ) Research Conducted within the Federal Bureau of Prisons (BOP) can be found in the "Additional Requirements for Department of Justice (DOJ) Research Conducted within the Federal Bureau of Prisons (BOP)" section in the IRB's "WORKSHEET: Additional Federal Criteria (HRP-318)."

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**Additional Requirements for DOJ Research Funded by the National Institute of Justice**

1. The project must have a privacy certificate approved by the national Institute of Justice Human Subjects Protection Officer.

2. All investigators and research staff are required to sign employee confidentiality statements, which are maintained by the responsible investigator.

3. The confidentiality statement on the consent document must state that confidentiality can only be broken if subject reports immediate harm to subjects or others.

4. Under a privacy certificate investigators and research staff do not have to report child abuse unless the subject signs another consent document to allow child abuse reporting.

5. 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.

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**Institutional Review Boards authorized to review research**

For information regarding IRBs that are able to review human subject research on behalf, please visit: https://science.energy.gov/ber/human-subjects/irbs/

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**Revision History**

Modified 03/20/2018