Saint Louis University Institutional Review Board

Additional Criteria for Department of Justice (DOJ) Research

(*Check if “Yes” or “N/A.” Note: all must be checked for final approval.)*

**Additional Criteria if Conducted within the National Institute of Justice (NIJ)**

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|  | The name(s) of the funding agency(ies) are listed in the protocol and consent document. |
|  | All members of the research team have been educated about the specific requirements of DOJ research funded by NIJ. |
|  | A study privacy certificate has been approved by the NIJ human subjects protection officer. |
|  | All members of the research team have signed employee confidentiality statements and the statements are being maintained by the PI. |
|  | The confidentiality statement in the consent document states that confidentiality can only be broken if the subject reports immediate harm to research subjects or others. |
|  | The research team and study members have been informed that, under a privacy certificate, the research team does not have to report child abuse unless the research subject signs another consent document to allow child abuse reporting. |
|  | A copy of all data will 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. |
|  | 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. |

**Additional Criteria if Conducted within the Bureau of Prisons (BOP)**

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|  | The protocol does **not** involve medical experimentation, cosmetic research, or pharmaceutical testing.  *Note: Research involving the aforementioned cannot be conducted within the BOP.* |
|  | The protocol has been reviewed by the BOP Bureau Research Review Board (BRRB). |
|  | The protocol clearly illustrates that the research design is compatible with both the operation of prison facilities and protection of human subjects. |
|  | All members of the research team have been educated about the specific requirements of DOJ research within the BOP and have agreed to observe the rules of the institution or office in which the research is conducted. |
|  | All investigators who are not BOP employees have signed a statement agreeing to comply with the requirements of 28 CFR 512 and the statements are being maintained by the PI. |
|  | The principal investigator has academic preparation or experience in the area of study of the proposed research. |
|  | The protocol contains all of the following (MUST check all):  A statement regarding assurances and certification required by [28 CFR part 46](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html);  A statement assuring that principal investigator assumes responsibility for actions of any person participating in the research as an associate, assistant, or subcontractor;  A clear outline of the methods by which an equitable selection of subjects within any one organization will be performed;  An adequate research design and a clear outline of the ways in which the research will contribute to the advancement of knowledge about corrections;  Assurance that records containing non-disclosable information directly linkable to a specific person will not be stored in, or introduced into, an electronic retrieval system.  *Note: Computerized data records maintained in an official Department of Justice site are exempt from this requirement. However, this situation must be made clear in the protocol.* |
|  | A non-employee of the BOP will receive research records in a form not individually identifiable and the BOP has been provided with advance adequate written assurance that the record will be used solely as a statistical research or reporting record. |
|  | The research team will not provide research information that identifies a subject without that subject’s prior written consent to release the information, except as noted in the consent statement. |
|  | The protocol includes a summary statement containing all of the following (MUST check all):  Names and current affiliations of the investigators;  Title and purpose of the study;  Location of the study;  Methods to be employed;  Anticipated results;  Duration of the study;  Number of subjects (staff or inmates) required and amount of time required from each;  Indication of risk or discomfort involved as a result of participation. |
|  | The protocol includes a comprehensive statement containing all of the following (MUST check all):  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[[1]](#footnote-1);  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;  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;  Description of physical or administrative procedures to be followed to destroy research records or remove individual identifiers from those records when the research has been completed. |
|  | Incentives will not be offered to help persuade inmate subjects to participate.  *Note: Soft drinks and snacks to be consumed at the test setting may be offered. Reasonable accommodations such as nominal amounts for time and effort may be offered to non-confined research subjects who are no longer in BOP custody and are participating in research being conducted by BOP employees or contractors.* |
|  | The study consent form includes a disclosure statement containing all of the following (MUST check all):  Clear identification of the investigators;  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;  A statement that participation in the research project will have no effect on the inmate subject's release date or parole eligibility;  A statement regarding outlining the anticipated uses of the results of the research;  A statement regarding the confidentiality of the research information and exceptions to any guarantees of confidentiality required by federal or state law. |
|  | At least once a year, the PI shall provide the Chief, Office of Research and Evaluation, Central Office, Bureau of Prisons, with a report on the progress of the research. |
|  | Prior to submission for publication, 2 copies of the research material will be provided to the Chief, Office of Research and Evaluation, Central Office, BOP. These copies will be for informational purposes only. |
|  | At least 12 working days before any report of findings is to be released, the PI 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. |
|  | All reports of finding shall include an abstract and acknowledge the BOP’s participation in the research. |
|  | All publications of results shall disclaim approval or endorsement of the published material as an expression of the policies or views of the BOP. |
|  | If the project is of special interest to the ORE, the researcher may be asked to provide the ORE with de-identified electronic data and detailed documentation. This should be determined prior to data collection. |

1. Required resources will vary with each protocol. PIs should consult with their DOJ Project Officer to determine any additional required documents. [↑](#footnote-ref-1)