Issuing Department: Human Subjects Protection Program (HSPP)
Policy Number: 2014-028.0
Policy Title: Additional Requirements – National Institute of Justice

Purpose

The purpose of this policy is to set forth additional requirements that are applicable to research supported by the National Institute of Justice (NIJ). NIJ is a component of the Office of Justice Programs within the Department of Justice.

Definitions

See policy 2011-007.0 for definitions of Privacy Certificate

Policy

For NIJ-funded research:

- all projects are required to have a privacy certificate approved by the NIJ human subjects protection officer;
- all researchers and research staff are required to sign employee confidentiality statements, which are maintained by the responsible researcher.

The consent form must:

- identify the National Institute of Justice as the funding agency.
- include a statement describing the extent to which confidentiality of records identifying the subject will be maintained.
- inform the subject that private, identifiable information will be kept confidential and will only be used for research and statistical purposes.
- 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 researcher 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.

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.

At least once a year, the investigator shall provide the chief, Office of Research and Evaluation, with a report on the progress of the 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.

At least 12 working days before any report of findings is to be released, the investigator 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 investigator shall include an abstract in the report of findings.

In any publication of results, the investigator shall acknowledge the Bureau's participation in the research project.

The investigator 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 investigator shall provide two copies of the material, for informational purposes only, to the Chief, Office of Research and Evaluation, Central Office, Bureau of Prisons.

Procedure

Investigators who have obtained funding from National Institute of Justice are required to complete and submit Appendix H which address the additional requirements of NIJ.

When developing the consent form, investigators are to use the consent checklist addendum specific to NIJ funded research to ensure the additional required elements of consent have been incorporated into the consent form. The consent form and checklist are submitted to the IRB.

IRB Regulatory Specialist will screen submissions, using the checklists as a tool, to ensure required documents have been provided.

IRB members will be expected to evaluate the National Institute of Justice Addendum and consent forms to determine whether the National Institute of Justice Requirements have been met such that the research may be approved.

Related Policies

2011-008.0 – Informed Consent Forms
2011-008.5 – Providing and Obtaining Informed Consent
2011-009.3 - Institutional Review Board – Expedited Reviews
2011-009.5 – Institutional Review Board - Review by Convened Board
2011-009.12 – Institutional Review Board – Criteria for Approval

Basis

28 CFR 22
28 CFR 46

Document Attributes

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Replaced Version: 6/14/2017

Reviewed and Approved By:

Richard H. Simon ***11/1/2023***
Richard H. Simon, MD **Date**
Director, Human Subjects Protection Program