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.

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.

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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**Richard H. Simon** 15 June 2017
Richard H. Simon, MD Date
Director, Human Subjects Protection Program