

I. Overview

Human subjects research funded by the U.S. Department of Justice (DOJ), including the National Institute of Justice, must comply with additional requirements in order to be approved by the VDSS IRB.

II. Definitions

Research or statistical project means any program, project, or component thereof which is supported in whole or in part with funds appropriated under the Omnibus Crime Control and Safe Streets Act of 1968 and whose purpose is to develop, measure, evaluate, or otherwise advance the state of knowledge in a particular area. The term does not include “intelligence” or other information-gathering activities in which information pertaining to specific individuals is obtained for purposes directly related to enforcement of the criminal laws.

Private, identifiable information means information is either 1) labeled by name or other personal identifier, or 2) can, by virtue of sample size or other factors, be reasonably interpreted as referring to a particular private person.

III. Regulatory Requirements

28 CFR 46	Protection of Human Subjects
28 CFR 22	Confidentiality of Identifiable Research and Statistical Information
42 U.S.C. 3789g	Confidentiality of Information
45 CFR 46, Subpart D	Protection of Human Subjects

IV. Scope of Guidance Document

This Guidance Document applies to all on-going and future human subjects research activities conducted or authorized by VDSS, local departments of social services, VDSS-licensed facilities, or VDSS-authorized contractors.

V. Specific Additional Requirements

In addition to the requirements specified in 45 CFR 46, the VDSS IRB must consider the following requirements when reviewing non-exempt human subjects research funded by the DOJ.

A. Privacy Certificate [28 CFR 22; 42 USC 3789g]

Applicants for DOJ funding must submit a Privacy Certificate as a condition of approval of a grant application or contract proposal regardless of whether the project involves the collection of identifiable data. Privacy Certificate Resources:

1. [NIJ Privacy Certificate Requirements](#)
2. [NIJ Privacy Model Privacy Certificate](#)

B. Confidentiality

For NIJ-funded research, all researchers and research staff are required to sign employee confidentiality statements, which are maintained by the responsible researcher.

C. Informed Consent – Additional Requirements [28 CFR 46.116]

When funded by the DOJ, the informed consent must disclose all of the following:

1. The particular types of information that will be collected.
2. Private, identifiable information will only be used for research and statistical purposes. Any intended disclosures for research purposes must be explicitly identified in the informed consent document including what will be disclosed, under what circumstances, and to whom.
3. The confidentiality statement in the informed consent document should disclose that confidentiality may be broken if the subject indicates future criminal intent.
4. Participation in the research and provision of private identifiable information is voluntary and may be terminated at any time.
5. Project findings and reports prepared for dissemination will not contain information which can reasonably be expected to be identifiable.
6. If applicable, where findings in a project cannot, by virtue of sample size or uniqueness of subject, be expected to totally conceal subject identity, this must be included in the informed consent.
7. If funded by the National Institute of Justice:
 - a. Statement that the study is funded by the National Institute of Justice (NIJ).
 - b. A copy of all data must be de-identified and submitted to the National Archive of Criminal Justice Data, including copies of the informed consent document, data collection instruments, surveys or other relevant research materials.

D. Reporting of Child Abuse

The Department of Justice regulations prohibit any disclosure of identifiable information, except where the researcher learns of intent to commit future criminal conduct. Virginia Code requires that all employees of institutions of higher education report actual or suspected child abuse to appropriate state agencies. When research is supported by the DOJ, in order to report child abuse, the researcher must obtain consent to allow child abuse reporting. The consent to allow reporting should be obtained at the time of enrollment in the study using either a separate consent document or incorporated in the research consent document.

VDSS IRB NOTE: If the research involves interaction between prospective research participants and a person(s) required¹ to report suspected child abuse or

¹ Code of Virginia § 63.2-1509. Requirement that certain injuries to children be reported by physician, nurses, teachers, etc., penalty for failure to report

neglect; then, any prospective research participant who does not voluntarily give consent to allow child abuse reporting cannot participant in the research study.

Example of consent to report language: In the unlikely event that in the course of this research your child tells us that he or she is experiencing abuse or research staff sees that your child is in a situation that may be dangerous or harmful; we would like your permission to let appropriate authorities know. If a report is made, you may be contacted to determine your child's safety. We must have your written permission before we could make such a report. You have the right to provide permission. However, you and your child will not be able to take part in this research study without it.

Example of language to add to the consent form signature page: I hereby give consent for my child or child for whom I am the legal guardian to participate in the research and to allow reporting of suspected or actual child abused or neglect. I understand this process is voluntary and that the child or I can stop answering questions at any time. I can walk away from the study at any time. There is no penalty if I do not answer questions or decide to walk away from the study.

The National Institute of Justice provides a [template consent](#) for this purpose. The IRB must ensure that the research informed consent language does not conflict with this DOJ policy.

E. Archiving of National Institute of Justice Data

Projects funded by the National Institute of Justice are required to submit de-identified data to the National Archive of Criminal Justice Data, including copies of the informed consent document, data collection instruments, surveys, and other relevant research materials. Plans for submitting data should be described in the Data Archiving Plan and approved by the NIJ grant manager. For more information, see NIJ funding information².

F. Research Conducted Within the Federal Bureau of Prisons

For research conducted within the Bureau of Prisons, the researcher must assume responsibility for actions of any person engaged to participate in the research project as an associate, assistant, or subcontractor to the researcher. Please note, in general, VDSS does not conduct research in the Federal Bureau of Prisons. Exceptions require approval from the VDSS Commissioner.

² <https://www.nij.gov/funding/data-resources-program/applying/Pages/data-archiving-strategies.aspx>