Status Active PolicyStat ID 13320891

Boston Children's Hospital

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Effective 1/1/2023

Next Review 1/1/2026

Owner Susan Kornetsky: Manager

Department Research

Applicability Boston Children's Hospital- Policies & Procedures

Research Involving Department of Justice Funding Policy/ Procedure

Internal Approval

SVP, Research

EVP & Chief Scientific Officer, Research

Scope

The policy provides information and guidance on the additional procedures required when human subject research is conducted with support from any program or involves any component of the Department of Justice (DoJ).

Definitions

As defined by DoJ:

Human Subjects Research: DoJ applies the standard Common Rule (45 CFR 46) definition of Human Subjects Research. DoJ regulations provide the following additional information:

Research is also defined as any program, project, or component thereof which is supported by DoJ and whose purpose is to develop, measure, evaluate, or otherwise advance the state of knowledge in a particular area. [28 CFR 22.2(c)]

Identifiable private information: Defined by DoJ as information not extracted from public records which:

- Is labeled by name or other personal identifiers, **or**
- Can, by virtue of sample size or other factors, be reasonably interpreted as referring to a particular private person.

National Institute of Justice: The DoJ program that funds most DoJ Human Subjects Research.

Office of Justice Programs: An umbrella organizational structure within the DoJ, under which most DoJ research programs reside.

Privacy Certificate: A requirement for all human subjects research supported by the NIJ and assures that the grant applicant understands their responsibilities to protect the confidentiality of research and statistical information and has developed specific procedures to ensure that this information is only used or revealed in accordance with the requirements of 42 USC §3789g and 28 CFR Part 22.

Under a Privacy Certificate, the regulations that govern DoJ funded research do not allow the researcher and/or research staff to make voluntary disclosures of matters such as current or past abuse or risk of harm to oneself or others. However, Massachusetts child and elder abuse reporting laws require the researcher to make these disclosures.

In order to comply with both the regulations that govern DoJ funded research and the state reporting requirements, the researcher must provide a second informed consent (addendum) to allow such reporting, should a subject self-disclose give staff strong reasons to believe the subject may be in a dangerous situation. Here is a ***sample consent***.

Policy Statements

Boston Children's Hospital's (BCH) Institutional Review Board (IRB) ensures that applicable DoJ requirements are appropriately addressed before it grants IRB approval. Research is considered to be conducted with support from or to involve a component of the DoJ when it:

1. Is funded by the DoJ (most often from the National Institute of Justice (NIJ).
2. It involves the cooperation, collaboration, or other type of agreement with DOJ, including sites, institutions, personnel.

   For example, research conducted within any facilities of the Bureau of Prisons (BOP) must comply with the specific BOP requirements.
3. It uses or is supported by property, facilities, or assets of a component of DoJ.

   For example, the Bureau of Justice Statistic or National Center for Juvenile Justice.

Background

Human subject research which is supported or funded by NIJ is governed by the DoJ regulations for the protection of human subjects (28 CFR 46: The Common Rule) and the DoJ Confidentiality of Identifiable Research and Statistical Information regulations (28 CFR 22). Together, these regulations:

- Protect the privacy of individuals by limiting the use of private, identifiable information for research or statistical purposes.
- Protect private information provided by individuals from use in any judicial, legal, or administrative process without the individual's prior consent.
- Improve the scientific quality of NIJ research programs by minimizing the subject's concerns

over the use of the data.

- Clarify for researchers the limitations on the use of privately identifiable information for only research or statistical purposes.
- Ensure that our understanding and knowledge of the broad criminal justice system will continue to advance by providing individual privacy protections.

Procedures

Requirements for Investigators Conducting DoJ Research:

Investigator Requirements for research funded by NIJ:

1. **Sign an Employee Confidentiality Statement.** All researchers and research staff are required to sign employee confidentiality statements as a condition of grant or proposal approval by the NIJ. Certificates are maintained by the responsible Research Investigator. Here is the ***NIJ Model Employee Confidentiality Statement***.
2. **Obtain a Privacy Certificate and submit it to the IRB with application.** Once obtained, the IRB will review the Privacy Certificate to ensure the confidentiality protections described in the Privacy Certificate are consistent with the confidentiality protections described in the IRB application and Informed Consent form. Investigators should refer to the ***NIJ Privacy Certificate Guidance and Model Privacy Certificate***.

   The information that must be included are the sample format and instructions to avoid common problems.

   Note: The NIJ only accepts the Privacy Certificate. It does not issue or accept Certificate of Confidentiality issued by the National Institutes of Health (NIH). Please see the separate IRB policy: ***Certificates of Confidentiality***.
3. **Keep Privacy Certificate Current and make necessary modifications.** If data collection methodology and/or information provided in the Privacy Certificate changes as a result of IRB requirements, a revised Privacy Certificate must be provided to the NIJ and IRB prior to the commencement of research.
4. **Accessing Military Volunteers: If BCH investigators seek to access military volunteers, they will need to do so in collaboration with a military researcher familiar with service-specific requirements.**
5. **Statements in Application.** When submitting a research protocol, the applicant must provide the following:
   a. A summary statement which includes:
      - Names and current affiliations of the investigators
      - Title of the study
      - Purpose of the study
      - Location of the study

- Methods to be employed
- Anticipated results
- Durations of the study
- Number of subjects (staff or inmates) required and the amount of time required from each
- Indication of risk or discomfort involved as a result of participation.

b. A comprehensive statement, which includes:
    - 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
    - Description of all possible risks, discomforts, and benefits to the individual subjects or a class of subjects, and a discussion of the likelihood that the risks and discomforts will actually occur
    - Description of the steps taken to minimize 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
        - Destroy research records or remove individual identifiers from those records when the research has been completed
    - Description of any anticipated effects of the research study on organizational programs and operations
    - Relevant research material such as vitae, endorsements, sample consent statements, questionnaires, and interview schedules
    - A statement regarding assurances and certification required by 28 CFR 46, if applicable.

6. **Include the following in the Informed Consent Form:**
    a. A statement describing the extent to which confidentiality of records identifying the subject will be maintained (the subject should be informed that private, identifiable information will be kept confidential and will only be used for research and statistical purposes. However, the subject should be made aware that a disclosure of future criminal intent is not covered or protected by DOJ regulations.

    b. Under a Privacy Certificate, researchers and research staff are not permitted to report current or past abuse or whether a subject is at risk for harming himself/herself or others. Since this is in conflict with requirements of Massachusetts law (and most other state laws), the investigator must provide a second informed consent (addendum) to allow for such reporting, should there be a self-disclosure or if the research staff has reasons to believe the subject may be in a dangerous

situation. Here is a ***NIJ Sample of the Consent for Reporting***.

If the research will be conducted outside of Massachusetts, the Office of General Counsel can advise on state law requirements in the state where the research will be conducted.

c. If, due to sample size or some unique feature, the identity of the individual cannot be maintained, the subjects need to be explicitly notified.

   If the investigator intends to disclose any information, the subject needs to be explicitly informed what information would be disclosed, under what circumstances, and to whom. The subject must be informed of any potential risks which may result from this disclosure.

d. Subjects must be informed that study is funded by NIJ.

e. 28 CFR 46.117 allows for waiver of documentation of informed consent where criteria met.

   For reference, the NIJ has provided Informed consent requirements ***NIJ Guidance on Informed Consent Requirements***.

7. **The Principal Investigator must submit IRB approval letter and the informed consent to NIJ or applicable funding agency.**
8. **PI Requirements and Responsibilities for research conducted within the Federal Bureau of Prisons:**
   a. 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 investigator.
9. **Archiving**: Follow guidelines to submit data resulting from their projects to NIJ for archiving with the National Archive of Criminal Justice Data (NACJD), including copies of the informed consent document, data collection instruments, surveys, or other relevant research materials.

   Except for computerized data/records maintained at an official DOJ site, records that contain non-disclosable information directly traceable to a particular person may not be stored in or introduced into an electronic retrieval system (such as the EMR).

Related Content

IRB Policy

- *Certificates of Confidentiality*

Regulatory Citations

- ***28 CFR 46***
- ***28 CFR 512***
- ***42 USC 3789g***

Federal Guidance

- ***NIJ Guidance on Informed Consent Requirements***
- ***NIJ Model Employee Confidentiality Statement***
- ***NIJ Privacy Certificate Guidance and Model Privacy Certificate***
- ***NIJ Sample of the Consent for Reporting***

Approval Signatures

Step Description	Approver	Date

Applicability

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