



**To:** Department of Health & Senior Services' Research Investigators  
**From:** Eliot Fishman, Director, Office of Policy  
**Date:** December 15, 2009  
**Subject:** Federal Certificate of Confidentiality

# MEMO

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This memorandum provides background and guidance on the privacy protections afforded research subjects participating in research covered by a Federal Certificate of Confidentiality ("Certificate"). The New Jersey Department of Health and Senior Services (the "Department") administers the following policies and guidances through the Office of Policy, Human Protections Administrator ("HPA").

For illustrative purposes, direct language from Federal statutes and regulations are italicized. A Frequently Asked Questions (FAQ) webpage on Certificates is hosted by the National Institutes of Health (NIH) at <http://grants.nih.gov/grants/policy/coc/faqs.htm>, with instructions and application materials available at <http://grants.nih.gov/grants/policy/coc/contacts.htm>.

## 1. BACKGROUND

The NIH are authorized by the Public Health Service Act to issue Certificates to research projects regardless of funding source. Certificates serve to protect research subjects' identifying information by authorizing "*persons engaged in biomedical, behavioral, clinical, or other research...to protect the privacy of individuals who are...participating in... such research by withholding from all persons not connected with the conduct of such research the names or other identifying characteristics of such individuals. Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals*" (42 U.S.C. 241(d)).

Investigators become engaged in research when they i) intervene with research subjects, ii) interact with research subjects or iii) use or maintain research subjects' identifying information (45 CFR 46.102(f)). Identifying information is defined as, "*the name, address, any identifying number, fingerprints, voiceprints, photographs or any other item or combination of data about a research subject which could reasonably lead directly or indirectly by reference to other information to identification of that research subject.*" (42 CFR 2a(2)(g)).

The privacy protection afforded by a Certificate "*...is permanent with respect to subjects who participated in the research during any time the authorization was in effect.*" (42 CFR 2a(8)(c)). However, this authorization does not extend to disclosures that are i) consented to by research subjects or their guardians, ii) required by the Federal Food, Drug and Cosmetic Act or regulations promulgated there under or iii) required by the U.S. Department of Health & Human Services (DHHS) for an audit, evaluation or investigation of DHHS-funded research (42 CFR 2a(4)(j)(3)).

In addition to a Certificate's privacy protections, the Federal regulations for the protection of research subjects also afford privacy protections, as principal investigators are required to provide an assurance on the Certificate's application that they will comply with all the requirements of 45 CFR Part 46 when conducting DHHS-funded research (42 CFR 2a(4)(g)(1)). Principal investigators whose research is not

DHHS-funded must provide an assurance on the Certificate's application that they will comply with the same informed consent requirements as DHHS-funded research (42 CFR 2a(4)(g)(2)).

Certificates do not prohibit the voluntary disclosure of research subjects' identifying information as described further below. They do however, prohibit disclosure of identifying information which would otherwise be compulsory under any statutory, regulatory, or common law requirement. (42 CFR 2a(4)(j)(4) and 42 CFR 2a(7)(c)). Certificates absolve Investigators from any legal compulsion to comply with any such requirements and provide immunity from any liability arising from his or her decision not to disclose voluntarily any such information.

Notwithstanding the foregoing prohibition, a Principal Investigator may, in his or her discretion, make a voluntary disclosure of such information, if it appears reasonably necessary for the health, welfare and protection of the persons involved. An investigator's voluntary disclosure of research subjects' identifying information is permissible only if the intention to make such a disclosure is explicitly stated in the Institutional Review Board (IRB)-approved informed consent document.

The following delineates the primary ethical obligations and regulatory requirements imposed upon investigators engaged in Certificate-protected research:

- 1.1. The Public Health Service Act at 42 U.S.C. 241(d) and Federal regulations at 42 CFR 2a et. seq. authorizes investigators to withhold research subjects' identifying information.
- 1.2. The Federal regulations at 42 CFR 2a(4)(i), 42 CFR 2a(4)(g), 45 CFR 46.111(a)(7), and the Certificate application as signed by the principal investigator and institutional official, require investigators to withhold research subjects' identifying information.
- 1.3. The ethical principles set forth in The Belmont Report (Respect for Persons, Beneficence and Justice) and the Federal regulations at 45 CFR 46.116(a)(2) and 45 CFR 46.116(a)(5), require investigators to comply with the terms of the IRB-approved informed consent document.
- 1.4. The Department's Federalwide Assurance (FWA-4020) with the U.S. Department of Health & Human Services and Federal regulations at 45 CFR 46.103(b)(1), require and obligate investigators to honor the privacy commitments made during the consent process.
- 1.5. The Certificate application as signed by the principal investigator and institutional official, and the Federal regulations at 45 CFR 46.116(a)(2), 45 CFR 46.116(a)(5) and 45 CFR 46.111(a)(7), require principal investigators to explicitly state in the informed consent document any circumstances under which research subjects' identifying information will be voluntarily disclosed, if any.

## **2. GUIDANCE**

It is the responsibility of each Principal Investigator requesting identifying information from the Department to obtain Certificates for all human subjects research involving personal health information where disclosure or misuse could harm research subjects' financial standing, employability, insurability, reputation, or other wise compromise the core principles set forth in the "Belmont Report."

Certificates are required for any for human subjects research on communicable diseases, birth defects, sexual preferences, drug use, mental health or genetic predisposition. Any proposed exceptions to the foregoing shall be submitted in writing to the Office of Policy for consideration and determination.

- 2.1. Investigators are responsible for seeking specific guidance from the Office of Policy prior to submission of any amended Certificate application to the NIH issuing authority.

- 2.2. The condition(s), if any, under which voluntary disclosures will be made must be explicitly stated in the informed consent document so that research subjects' decision to participate is predicated upon their fully informed acceptance of this privacy limitation.
- 2.3. Research subjects recruited prior to a Certificate's issuance must be informed of any new privacy protections afforded by such Certificate by providing revised informed consent documents, newsletters, or other informative materials. If it is for any reason impossible or impractical to contact such individuals, the Principal Investigator should contact the NIH issuing authority and the Office of Policy for advice.
- 2.4. Any request to release, transfer, inspect or disclose identifying information regarding research subjects participating in Certificate-Protected Research shall, in the first instance, be referred to the Principal Investigator by the recipient of the request.
  - 2.4.1 The Principal Investigator shall be responsible for promptly notifying the issuing NIH Certificate Coordinator and the DHSS Office of Policy of such request.
  - 2.4.2 The DHSS Office of Policy shall be responsible for advising the Department's Office of Legal & Regulatory Affairs (OLRA) on all such matters.
  - 2.4.3 The Principal Investigator shall, subject to any qualification or conditions imposed by the Office of Policy, OLRA and/or NIH Certificate Coordinator, advise the requesting party that:
    - (a) The research is protected by a Certificate of Confidentiality issued by the NIH;
    - (b) The request specifies protected identifying personal information which cannot be provided;
    - (c) Any non-identifying information requested will be provided in accordance with established DHSS procedures and policies; and
    - (d) That, upon request a copy of the Certificate and current IRB approval letter will be provided.
  - 2.4.4 In the case of any request made pursuant to any legal, administrative, legislative or regulatory authority, the foregoing response shall be made in writing, with copies to the Office of Policy, OLRA and NIH Certificate Coordinator.
  - 2.4.5 The Principal Investigator shall maintain a record of all requests, including name and contact information of the requesting party, date and time of the request, a summary description of the information requested, reason stated for the request, summary of all communications regarding the request, and statement of ultimate disposition.
- 2.5. Improper disclosure of protected research subjects' identifying information may result in reporting of the violation to the U.S. Department of Health and Human Services (45 CFR 46.103(b)(5)), suspension or termination of the project or the investigator's removal from the project, project suspension or termination, prohibition from participation in future DHSS research, and/or further administrative or legal action, including referral to the New Jersey Office of the Attorney General.
- 2.6. The Office of Policy is available to provide training and specific guidance on Federal Certificates of Confidentiality, as well as feedback on draft responses to formal requests for identifying information about research subjects.