

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH	Human Research Protection Program Policies & Procedures	
	Identification	Page 1 of 4
Title: Certificates of Confidentiality	Date Effective 11/15/04	Supercedes P&P dated

Background

Certificates of Confidentiality are issued by the National Institutes of Health (NIH) and other DHHS agencies to protect the confidentiality of information obtained from research subjects. They do this by protecting investigators and institutions from being compelled to release information about research subjects that is considered privileged because it is sensitive and identifiable. Certificates thus help to achieve the research objectives, promote participation in studies by assuring privacy to subjects, and ensure that subjects will not be harmed as a result of their taking part in research. A Certificate does not, however, take the place of good data security or clear policies and procedures for data protection, which are always essential to protect the privacy of research subjects.

(<http://www.grants.nih.gov/grants/policy/coc/background.htm>).

JHSPH Policy and Procedures

When Is a Certificate of Confidentiality Appropriate?

A JHSPH Principal Investigator who plans a study in which *sensitive and identifiable information* will be obtained should consider applying to a DHHS agency for a Certificate. By “sensitive”, DHHS means identifiable information which, if disclosed, could have adverse consequences for subjects or damage their financial standing, employability, insurability or reputation. Examples of sensitive information include, but are not limited to:

- Results of genetic tests;
- Information on the psychological state of subjects;
- Subjects’ sexual attitudes, preferences or practices; and
- Information about substance abuse or other illegal behaviors.

Projects *not* eligible for a Certificate are:

- Projects that are not research;
- Projects that do not collect personally identifiable information;
- Projects that are not reviewed and approved by an IRB; and

- Projects collecting information that, if disclosed, would *not* significantly harm or damage the subject.

The Research Plan should spell out the plans for obtaining a Certificate and explain why one is needed.

If JHSPH is the lead institution on a multi-site study or a coordinating center the Principal Investigator can apply for and receive a Certificate on behalf of all member institutions. The application must list each participating unit, its address, and project director. In addition, the lead site must indicate that it has on file a copy of the IRB approval and IRB-approved consent form(s) from each site, which will be made available to the granting agency upon request.

Protections Afforded by a Certificate

Certificates are issued to the institutions or universities where the research is conducted (see above for exception concerning multi-site research). Except as described below, they allow an investigator and others who have access to research records to refuse to disclose identifying information in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state or local level.

While Certificates protect against involuntary disclosure, subjects may voluntarily disclose, or request investigators to disclose, their research data or information. Subjects may, for example, authorize the investigator in writing to release the information to physicians, insurers, employers, or other third parties. In such cases, researchers may not use the Certificate to refuse disclosure.

Certificates do not, however, authorize researchers to refuse to disclose information about subjects if authorized DHHS personnel or authorized JHSPH reviewers request such information for an audit or program evaluation. Neither can researchers refuse to disclose such information if it is required to be disclosed by the Federal Food, Drug, and Cosmetic Act.

Researchers are also not prevented from disclosure of child abuse, reportable communicable diseases, or a subject's threat of violence to self or others. *If, however, the researcher intends to make such disclosures, that must be clearly stated in the consent form.*

Mandatory Reporting Requirements

JHSPH researchers are expected to comply with State and Local requirements to report communicable diseases, and also to meet other requirements, such as reporting suspected child abuse. Any researcher desiring not to comply with reporting requirements must justify the request to CHR and obtain CHR approval of the non-disclosure plan. Requests must be based on the welfare and rights of the subjects.

In the non-disclosure plan the investigator must describe either:

- An agreement that the applicant has made with the health department to cooperate in ways that serve the purposes of communicable disease reporting requirements, or

- The specific reasons related to confidentiality requirements of the research that preclude such reporting.

When physicians conducting research also provide clinical care for the subjects in a non-research relationship, the protections of the certificate do not apply and those physicians are considered the referring physicians for purposes of this policy.

For further guidance on required reporting see [Reportable Diseases and Conditions](#).

Requirements for Informed Consent

The consent form must inform subjects that a Certificate is in effect and must describe both the protections afforded by the Certificate and any limitations or exceptions to this protection. If the investigators apply for a Certificate *before* CHR approves the study, or intend to apply for one after CHR approval, the consent form(s) submitted for CHR review should state that a Certificate will be obtained and the protections afforded by the Certificate should be stated. (**SEE SAMPLE LANGUAGE**). The Certificate should not, however, be represented as an endorsement of the study by the DHHS or as a means of coercing recruitment of subjects. If JHSPH is the lead institution on a multi-site study or a coordinating center and holds a Certificate for the collaborating institutions, the consent form(s) for each site must describe the protections and limitations of the Certificate.

Investigators who decide to apply for and obtain a Certificate after CHR approval of their study, must notify subjects of the protections provided by the Certificate. This should be done by a consent addendum, for already enrolled subjects, and a revised consent form that includes the appropriate language concerning the Certificate for new enrollees.

Foreign Studies

If the data obtained from a study done outside the U.S. are maintained within the U.S., a researcher may obtain a Certificate. If the data are only maintained in a foreign country, a Certificate's legal protections are not effective.

Applying for a Certificate of Confidentiality

Application for a Certificate of Confidentiality should be made after CHR reviews and approves the research plan. This is because certificates will not be issued until CHR approval has been obtained. Approximately three months should be allowed for receipt of the Certificate. Investigators may apply for a Certificate by completing the application found at the Certificates of Confidentiality Kiosk at <http://grants1.nih.gov/grants/policy/coc/>. Investigators should review the instructions and other information concerning Certificates at the Kiosk.

Definitions

Identifying information is broadly defined as any item or combination of items in the research data that could lead directly or indirectly to the identification of a research subject. 46.102(f)(1)

Private information includes information about behavior which an individual can reasonably expect to be private. 46.102(f)(2)

Resources & References

Under section 301(d) of the Public Health Services Act (42 U.S.C.) 241(d) the Secretary of Health and Human Services may authorize person engaged in biomedical, behavioral, clinical, or other research to protect the privacy of individuals who are the subjects of that research. This authority has been delegated to the National Institutes of Health.