

DEPARTMENT: INSTITUTIONAL REVIEW BOARD  
POLICY NUMBER: 028  
SECTION: GENERAL IRB POLICIES  
REVIEW RESPONSIBILITY: IRB  
EFFECTIVE DATE: AUGUST 13, 2003  
REVISION DATE:  
LAW IMPLEMENTED: 45 CFR 46.111

SUBJECT: Certificate of Confidentiality

1. When an Investigator will be performing data collection about sensitive issues (such as illegal behavior, alcohol or drug use, or sexual practices or preferences), such a study requires the protection of confidentiality beyond preventing accidental disclosures. Under federal law, researchers can obtain an advance grant of confidentiality, known as a Certificate of Confidentiality, that will provide protection against compulsory disclosure, such as a subpoena, for research data. The Investigator should describe in the IRB application any conditions under which confidential information might be disclosed and create an informed consent document that accurately reflects those conditions, including any voluntary disclosure by the researcher. The IRB is required to determine whether the risks to subjects are minimized, informed consent is appropriate, and privacy and confidentiality protections are adequate.
2. A Certificate of Confidentiality provides protection for the researcher and the subjects against compelled disclosure of identifying information about subjects of biomedical, behavioral, clinical, and other research. See Public Health Service Act 301(d), 42 U.S.C. 241 (d). Under this Act, the Secretary of HHS may authorize persons engaged in research to protect the privacy of subjects by withholding from all persons not connected with the conduct of the research, the names or other identifying characteristics of the subjects. This means that researchers may not be compelled in any federal, state or local civil, criminal, administrative, legislative, or other proceedings to identify their subjects.
3. The protection is available only when the research is of a sensitive nature where protection is judged necessary to achieve the research objectives.
4. Research can be considered sensitive if it involves the collection of information in the following categories:
  - a) Information relating to sexual attitudes, preferences, or practices;
  - b) Information relating to the use of alcohol, drugs or other addictive products;
  - c) Information pertaining to illegal conduct;

- d) Information that if released could reasonably be damaging to an individual's financial standing, employability, or reputation within the community;
  - e) Information that would normally be recorded in a patient's medical record, and the disclosure of which could reasonably lead to social stigmatization or discrimination;
  - f) Information pertaining to an individual's psychological well being or mental health;
  - g) Genetic information.
5. Note that the Confidentiality Certificate does not govern the voluntary disclosure of identifying characteristics of research subjects but only protects from compelled disclosure of identifying characteristics by the researcher. Researchers, therefore, are not prevented from the voluntary disclosure of matters such as child abuse or a subject's threatening violence to self or others. However, if a researcher intends to make such voluntary disclosures, the consent form should clearly indicate this.