

**I. Policy**

It is the policy of the Department of Health (DOH) Institutional Review Board (IRB) to assure that the privacy and confidentiality protections are adequate for all research participants, which may include requesting the Investigator to secure a Certificate of Confidentiality.

**II. Authority**

- A. Chapter 381.86, Florida Statutes, Institutional Review Board

**III. Supportive Data**

- A. NIH Frequently Asked Questions on Certificates of Confidentiality, Web Posting: July 22, 2003
- B. Public Health Service Act 301(d), 42 U.S.C.241(d)
- C. OHRP Guidance Document, "Guidance on Certificates of Confidentiality," February 25, 2003

**IV. Definitions**

- A. **Certificate of Confidentiality:** A document that provides additional protection of data from legal subpoena. The Certificate provides protection against compelled disclosure of identifying information or other identifying characteristics of a research participant enrolled in biomedical, behavioral, clinical, and other forms of sensitive research.
- B. **Sensitive Information:** Includes, but is not limited to, information relating to sexual attitudes, preferences, or practices; information relating to the use of alcohol, drugs, or other addictive products; information pertaining to illegal conduct; information, that if released, might be damaging to an individual's financial standing, employability, or reputation within the community or might lead to social stigmatization or discrimination; information pertaining to an individual's psychological well-being or mental health; and genetic information.

**V. Procedures**

- A. **Circumstances When a Certificate of Confidentiality May be Indicated**

Data collection about sensitive issues (such as illegal behavior, alcohol or drug use, or sexual practices or preferences) requires the protection of confidentiality beyond preventing accidental disclosures. Under Federal law, Investigators 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 Investigator. The IRB

is required to determine whether the risks to subjects are minimized, informed consent is appropriate, and privacy and confidentiality protections are adequate.

**B. Eligibility for a Certificate of Confidentiality**

Federal funding is not a prerequisite for requesting a Certificate of Confidentiality. Any research that collects personally identifiable, sensitive information and that has been approved by an IRB is eligible for a Certificate.

**C. Protections Provided by a Certificate of Confidentiality**

A Certificate of Confidentiality provides protection for the Investigator and the participants against compelled disclosure of identifying information about participants of biomedical, behavioral, clinical, and other research (Public Health Service Act '301(d), 42 U.S.C. '241(d)). Under this Act, the Secretary of Health and Human Services (HHS) may authorize persons engaged in research to protect the privacy of participants by withholding from all persons not connected with the conduct of the research the names or other identifying characteristics of the participant. This means that Investigators may not be compelled in any Federal, State or local civil, criminal, administrative, legislative, or other proceedings to identify their participants.

1. The protection is available only when the research is of a sensitive nature where the protection is judged necessary to achieve the research objectives.
2. Research can be considered sensitive if it involves the collection of information in the following categories:
  - a. Research on HIV, AIDS, and other STDs;
  - b. Information relating to sexual attitudes, preferences, or practices;
  - c. Information relating to the use of alcohol, drugs or other addictive products;
  - d. Information pertaining to illegal conduct;
  - e. Information that if released could reasonably be damaging to an individual's financial standing, employability, or reputation within the community;
  - f. Information that might lead to social stigmatization or discrimination if it were disclosed;
  - g. Information pertaining to an individual's psychological well being or mental health;
  - h. Research on behavioral interventions and epidemiologic studies; and

- i. Genetic information.
- 3. Examples of studies that would not qualify for a certificate of confidentiality are:
  - a. Projects that are not research based;
  - b. Projects that are not approved by an IRB in accordance with the NIH guidelines governing Certificates of Confidentiality;
  - c. Projects that do not collect sensitive information or information that might harm the research participants; or
  - d. Projects that do not collect personally identifiable information.

**D. Limitations of a Certificate of Confidentiality**

The Certificate of Confidentiality does not govern the voluntary disclosure of identifying characteristics of research participants but only protects participants from compelled disclosure of identifying characteristics by the Investigator. Investigators, therefore, are not prevented from the voluntary disclosure of matters such as child abuse or a subject's threatened violence to self or others. However, if an Investigator intends to make such voluntary disclosures, the consent form should clearly indicate this.

**E. Investigator's Responsibility for Assuring Confidentiality**

Investigators are responsible for assuring confidentiality of research data. If the Investigator is conducting research involving sensitive information, the IRB may require the Investigator to obtain a Certificate of Confidentiality. The Investigator is responsible for submitting a request for the Certificate of Confidentiality from the National Institutes of Health (NIH). Additional information and submission instructions are located on the NIH website:  
<http://grants.nih.gov/grants/policy/coc/contacts.htm>.

**VI. History Notes**

This is a new policy. The Office of Statewide Research, Ethics and Human Research Protections Program are responsible for this policy.

**VII. Signature Block with Effective Date**



John O. Agwunobi, M.D., M.B.A., M.P.H.  
Secretary, Department of Health

06/29/05  
Date