



**Nova Southeastern University  
Standard Operating Procedure for GCP**

<b>Title: <u>Certificates of Confidentiality</u></b>		<b>Version # 1</b>
<b>SOP Number: OCR-PRIV-002</b>	<b>Effective Date: August 2013</b>	<b>Page 1 of 3</b>

**PURPOSE:** Particular attention is given to studies in which data is being collected about sensitive issues (such as illegal behavior, alcohol or drug use, or sexual practices or preferences) and may require special protection of the subjects' confidentiality. There have been instances where the identities of subjects or research data about particular subjects have been sought by law enforcement agencies, sometimes under subpoena, and with the threat of incarceration of the uncooperative researcher. Under federal law (and some state laws), researchers can obtain a "Certificate of Confidentiality" which is an advance grant of confidentiality that will provide protection from compelled release of research data, even against a subpoena.

**POLICIES:**

1. Certificates of Confidentiality issued by the National Institutes of Health, if not part of the submitted research plan, can be recommended by the Center/College or required by the IRB for biomedical, behavioral, clinical or other types of research that is "sensitive."
  - 1.1. "Sensitive" means that disclosure of identifying information could:
    - 1.1.1. Have adverse consequences for subjects; OR
    - 1.1.2. Damage their financial standing, employability, insurability, or reputation.
  - 1.2. Examples of sensitive research activities include but are not limited to the following:
    - 1.2.1. Collecting genetic information;
    - 1.2.2. Collecting information on psychological well-being of subjects;
    - 1.2.3. Collecting information on subjects' sexual attitudes, preferences or practices;
    - 1.2.4. Collecting data on substance abuse or other illegal risk behaviors;

- 1.2.5. Studies where subjects may be involved in litigation related to exposures under study (e.g., breast implants, environmental or occupational exposures).
2. In the event a study meets the criteria for a Certificate of Confidentiality but the sponsor has not provided one, the Center/College shall apply to NIH (and/or state or other federal agency as appropriate) for the Certificate. NOTE: The application to NIH by the investigator for the Certificate of Confidentiality requires a copy of the IRB approval of the study and an informed consent form with the language as if a Certificate of Confidentiality had been obtained. The IRB may give conditional approval pending the receipt of a Certificate of Confidentiality for projects involving Certificates of Confidentiality. The IRB may also give approval of an alternate Informed Consent Document in the event the NIH department does not honor the request for Certificate, if the IRB has considered the risks and has voted in the alternative, to approve the study if a Certificate is denied.

### **Procedure for Obtaining a Certificate of Confidentiality**

1. If the criteria for a Certificate of Confidentiality are met, the Center/College shall apply for one.
2. If the request is denied, the IRB should be notified and the IRB and Center/College should determine:
  - 2.1. what additional protections, if any, may be needed along with adequate disclosure in the consent form that the information may be released by subpoena
  - 2.2. to not conduct the study.
3. If a Certificate is obtained, the study personnel must inform participants in the informed consent document of the following:
  - 3.1. The existence of the Certificate of Confidentiality;
  - 3.2. What it is;
  - 3.3. The effective date; and the expiration date;
  - 3.4. A statement that data gathered during the time the Certificate of Confidentiality is in effect is still protected after the Certificate expires;
  - 3.5. A description of identifiable information involved in the study; and
  - 3.6. The circumstances in which voluntary disclosures would be made, disclosures such as:
    - 3.6.1. Child abuse reports
    - 3.6.2. Communicable disease reports
    - 3.6.3. Subject's threatened violence to self or others
    - 3.6.4. DHHS audit or program evaluation requests
    - 3.6.5. Information required to be disclosed by the Federal Food, Drug, and Cosmetic Act.

- 3.7. Although a Certificate is in place, the subject may request, in writing, the disclosure of identifying information.
4. The Center/College should submit requests for modifications, amendments, and extensions at least three months prior to the date needed and should be accompanied by a reason for requesting it and documentation of the most recent IRB approval.
  5. If there are significant modifications to the project or the informed consent form, this should be submitted to the issuing agency (i.e. NIH) so that they may consider modification to the existing Certificate of Confidentiality.
  6. If the project is not completed in the time specified in the application for the Certificate, the Center/College should apply for an extension to the expected date of completion of the project.

[www.nova.edu/irb/manual/confid.html](http://www.nova.edu/irb/manual/confid.html)