I. PURPOSE

To document the policies concerning certificates of confidentiality (COC).

II. SCOPE

This SOP applies to all studies approved by the UTHSC IRB.

Personnel Responsible:

University of Tennessee Health Sciences Center Institutional Review Board administrative staff and members.

III. BACKGROUND

Under the Public Health Service Act §301(d), 42 U.S.C. §241(d), the Secretary of the Department of Health and Human Services may authorize persons engaged in biomedical, behavioral, clinical, or other research to protect the privacy of individuals who are the subject of such research by withholding from all persons not connected with the conduct of such research the names or other identifying characteristics (see below) of such individuals. The privacy of the research subjects referred to in §301(d) is protected through the issuance of Certificates of Confidentiality (COC). Persons authorized under a COC 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. By protecting researchers and institutions from being compelled to disclose information that would identify research subjects, COCs help to minimize risks to subjects by adding an additional layer of protection regarding confidentiality.

The protection afforded by COCs is not limited to federally supported research. Researchers may obtain certificates of confidentiality provided that a determination is made that the research is of such a sensitive nature that protection is necessary to perform the research. Certificates are issues by the National Institutes of Health and other HHS agencies.
Sensitive Information
HHS has determined that research may be considered sensitive if it involves the collection of any of the following types of information:

- Information related to sexual attitudes, preferences, or practices;
- Information related to the use of alcohol, drugs, or other addictive substances;
- Information pertaining to illegal conduct;
- Information, that if released, could reasonably be damaging to an individual’s financial standing, employability, or reputation in the community;
- Information that would normally be recorded in the patient’s medical record, and the disclosure of which could reasonably lead to social stigmatization or discrimination;
- Information pertaining to psychological wellbeing or mental health;
- Information pertaining to the diagnosis and/or treatment of communicable diseases; and
- Genetic information.

Identifying Characteristics
Identifying characteristics include things such as: name, address, social security or other identifying number, fingerprints, voiceprints, photographs, genetic information or tissue samples, or any other item or combination of data about a research participant which could reasonably lead, directly or indirectly by reference to other information, to identification of that research subject.

Other Federal agencies may evaluate applications for certificates of confidentiality using different criteria.

Protections Provided by Certificates of Confidentiality
Researchers can use a COC to avoid compelled "involuntary disclosure" (e.g., subpoenas) of names and other identifying information about any individual who participates as a research subject (i.e., about whom the investigator maintains identifying information) during any time the Certificate is in effect. It does not protect against voluntary disclosures by the researcher, but those disclosures must be specified in the informed consent form. A researcher may not rely on the COC to withhold data if the participant consents in writing to the disclosure. Furthermore, COC do not prevent other types of intentional or unintentional breaches of confidentiality. As a result, investigators and IRBs must ensure that other appropriate mechanisms and procedures are in place to protect the confidentiality of the identifiable private information to be obtained in the proposed research.

Length of Protection
Individuals who participate as research subjects (i.e., about whom the investigator maintains identifying information) in the specified research project during any
time the COC is in effect are protected permanently— even if the subject gave the researcher data before the COC is issued.

In accordance with:

Public Health Service Act § 301(d), 42 U.S.C. § 241(d).

OHRP Guidance on Certificates of Confidentiality (02/25/2003)


Compliance with this policy also requires compliance with state or local laws or regulations which provide additional protections for human subjects.

IV. PROCEDURES

1. Investigators may voluntarily seek, or the UTHSC IRB may require an investigator to obtain, a DHHS Certificate of Confidentiality (COC) for research of a sensitive nature.
   a. Applications must be made for each specific protocol. OHRP’s website contains a list of contacts for different federal agencies concerning COCs located at http://www.hhs.gov/ohrp/policy/certconf.html.
   b. COCs are not transferable from one protocol to another.
   c. COCs are effective the date issued; investigators must obtain an extension from DHHS if the COC will expire prior to study completion. This request for an extension must occur at least 3 months prior to the expiration date on the certificate.
   d. If a researcher intends to make voluntary disclosures of confidential information, the consent form should clearly indicate the specific limitations that will be placed on the protection of confidentiality.

2. If the UTHSC IRB determines that a COC is necessary to minimize risks to human subjects, final approval of the study will be granted; however, subjects may not be enrolled and subject data may not be collected until such a COC is obtained, submitted to the IRB for review, and acknowledged by the IRB. NOTE: Generally, an application for a COC is submitted to DHHS after an IRB approves a study. You may state in your application that you will obtain a COC and include the corresponding UTHSC IRB consent form template.
language in the consent form that you will submit for IRB review and approval.

3. A copy of any COC and/or any amendments to such an application must be submitted to UTHSC IRB. In addition, the renewed COC showing the new expiration date must be submitted to the UTHSC IRB promptly during the course of the study.

4. If an investigator obtains a COC for a previously approved study, then the investigator must submit to the UTHSC IRB via iMedRIS a Form 2: Change Request and Amendments and include the following:
   a. Copy of the COC;
   b. Revised protocol (if applicable);
   c. Revised Form 1 Application;
   d. Revised informed consent document incorporating the COC language outlined in the UTHSC IRB consent form template at http://www.uthsc.edu/research/compliance/irb/researchers/consent-forms.php;
   e. Other pertinent documents.

5. Upon receipt of the study revision application, the UTHSC IRB will follow the procedures outlined in SOP: Revisions in Approved Studies.

6. Any COC or correspondence regarding it will be maintained with the study files.