UNIVERSITY OF TENNESSEE GRADUATE SCHOOL OF MEDICINE
INSTITUTIONAL REVIEW BOARD
CERTIFICATES OF CONFIDENTIALITY

I. PURPOSE

To document the policies concerning certificates of confidentiality (COC)

II. SCOPE

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

Personnel Responsible:

University of Tennessee Graduate School of Medicine Institutional Review Board (UTGSM IRB) administration and staff

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 (including research on mental health, including research on the use and effect of alcohol and other psychoactive drugs) 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 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.

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Researchers may obtain certificates of confidentiality only if a determination is made that the research is of such a sensitive nature that protection is necessary to perform the research. Protection against compelled disclosure is provided by the Secretary of Health and Human Services. Certificates of Confidentiality protect the privacy of individuals in any federal, state, local civil, criminal, administrative, legislative, or other proceedings.

OHRP 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 well-being or mental health
- Genetic information

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

Exceptions: DHHS personnel may request identifying information for purposes of audits, FDA, investigations of DHHS grant recipients or evaluating DHHS funded projects. In addition, policies on communicable disease reporting apply (OHRP IRB Guidebook at A5-45, 1993).

OHRP does not issue Certificates of Confidentiality. These are issued by the NIH and other HHS agencies to protect identifiable information from forced or compelled disclosures. 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.

Certificates of Confidentiality protect subjects from compelled disclosure of identifying information but do not prevent the voluntary disclosure of identifying characteristics of research subjects. Researchers, therefore, are not prevented from voluntarily disclosing certain information about research subjects, such as evidence of child abuse or a subject's threatened violence to self or others.

If a researcher intends to make such voluntary disclosures, the consent form should clearly indicate the specific limitations on the protection of confidential information. Furthermore, Certificates of Confidentiality 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.

REFERENCES

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

OHRP Guidance on Certificates of Confidentiality (2003) located at http://ohrp.osophs.dhhs.gov/humansubjects/guidance/certconf.htm

For more information on Certificates of Confidentiality and their limitations, see http://grants.nih.gov/grants/policy/coc/index.htm.

For Certificate of Confidentiality contacts at the National Institutes of Health, see http://grants.nih.gov/grants/policy/coc/contacts.htm.

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

IV. PROCEDURES

1. Investigators may voluntarily seek, or the UTGSM 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. (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 if the COC will expire prior to study completion.
   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 UTGSM IRB determines that a Certificate of Confidentiality is necessary to minimize risks to human subjects, the final approval of the study will not be granted until such a COC is obtained.

3. A copy of any Certificate of Confidentiality and/or any amendments to such an application must be submitted to UTGSM IRB.

4. If an investigator obtains a COC for a previously approved study, then the investigator must submit to the UTGSM IRB a Form 2: Change Request and Amendments and include the following:
   a. Copy of the COC;
   b. Revised protocol (if applicable);
   c. Revised informed consent document incorporating the COC language outlined in

the UTGSM IRB consent form template.

5. Any COCs or correspondence regarding them will be filed with the study files.