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 research 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.

All ongoing or new research funded by NIH as of December 13, 2016 that is collecting or using identifiable sensitive information is automatically issued a COC through a term and condition of award. 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.

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 not issued by OHRP, but are issued by the National Institutes of Health and other HHS agencies. Other Federal agencies may evaluate applications for certificates of confidentiality using different criteria.

For the purposes of this Policy, NIH considers research in which identifiable, sensitive information is collected or used, to include:

- Human subjects research as defined in the Federal Policy for the Protection of Human Subjects (45 CFR 46), including exempt research except for human subjects research that is determined to be exempt from all or some of the requirements of 45 CFR 46 if the information obtained is recorded in such a manner that human subjects cannot be identified or the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

- Research involving the collection or use of biospecimens that are identifiable to an individual or for which there is at least a very small risk that some combination of the biospecimen, a request for the biospecimen, and other available data sources could be used to deduce the identity of an individual;

- Research that involves the generation of individual level, human genomic data from biospecimens, or the use of such data, regardless of whether the data is recorded in such a manner that human subjects can be identified or the identity of the human subjects can readily be ascertained as defined in the Federal Policy for the Protection of Human "Subjects (45 CFR 46); or

- Any other research that involves information about an individual for which there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual, as defined in subsection 301(d) of the Public Health Service Act.

Disclosure is permitted only when:

- Required by Federal, State, or local laws (e.g., as required by the FDA, or state laws requiring the reporting of communicable diseases to State and local health departments), excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other preceding;

- Necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual;

- Made with the consent of the individual to whom the information document, or biospecimen pertains; or

- Made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research.

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).

For more information on Certificates of Confidentiality and their limitations, see https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html

For Certificate of Confidentiality contacts at the National Institutes of Health, see https://humansubjects.nih.gov/coc/contacts

Additional information such as FAQs are available at the NIH Certificates of Confidentiality website at https://humansubjects.nih.gov/coc/index.

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

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

PROCEDURES

1. All new research funded by NIH will automatically be issued a COC through the term and condition of the award.

2. 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.

3. 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.

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:
    - Documentation from the agency indicating the COC has been issued;
    - Revised protocol (if applicable);
    - Revised informed consent document incorporating the COC language outlined in the UTGSM IRB consent form template.