UNIVERSITY OF TENNESSEE GRADUATE SCHOOL OF MEDICINE
INSTITUTIONAL REVIEW BOARD
CONFIDENTIALITY IN HUMAN SUBJECT RESEARCH PARTICIPATION

I. PURPOSE

To document the policy and procedures used by University of Tennessee Graduate School of Medicine Institutional Review Board regarding the confidentiality of human subject participation.

II. SCOPE

This SOP applies to the IRB administrative staff and IRB members.

Personnel Responsible:

UTGSM IRB administrative staff and members

III. BACKGROUND

Confidentiality refers to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without express permission. The duty to protect confidential information reflects the right of persons to control access to information about themselves. Unauthorized disclosure of confidential information not only violates this right, but may place individuals at risk of damage to their financial standing, employability, or reputation, as well as place them at risk of criminal or civil liability.

HHS and FDA regulations for the protection of human subjects specify that IRB approval of research is contingent on the finding that "there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data." In addition, requirements for information disclosure in the informed consent process include "a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained."

It is the policy of UTGSM IRB that clinical research studies include procedures for assuring proper protection for the confidentiality of data and specimens secured from research participants, which must be outlined in the confidentiality section of the Form 1 application. Provisions for the protection of subject confidentiality must also be addressed in a separate section in all informed consent documents reviewed by UTGSM IRB.

In Accordance With:

45 CFR 46; 21 CFR 50, 56

OHRP IRB Guidebook located at:
http://www.hhs.gov/ohrp/archive/irb/irb_guidebook.htm

FDA Guidance for Institutional Review Boards and Clinical Investigators 1998 Update located at:

http://www.fda.gov/scienceresearch/specialtopics/runningclinicaltrials/guidancesinformationsheetsandnotices/ucm113709.htm

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

IV. PROCEDURES

1. UTGSM IRB will review the confidentiality section of all Form 1 applications to determine whether the provisions for and limitations on confidentiality delineated therein are consistent with the requirements of HSS regulations and all local, state and federal policies, regulations and laws (including the HIPAA regulations). The confidentiality section must define the manner in which subject identifiers will be used in research records, explain whether information about the subject's research participation will be placed in the medical record, include the HIPAA template securing subject authorization for the use of protected health information, and provide assurance that subjects will not be identified in any presentations or publications based on the results of the research.

2. The UTGSM IRB will review all submitted informed consent documents to ensure that the confidentiality section explains the provisions for and limitations on confidentiality pursuant to the requirements of HHS regulations and all local, state or federal policies, regulations and laws (including HIPAA regulations). The section on confidentiality must define the manner in which subject identifiers will be used in research records, explain whether information about the subject's research participation will be placed in the medical record, include the HIPAA template securing subject authorization for the use of protected health information, and provide assurance that subjects will not be identified in any presentations or publications based on the results of the research.

3. UTGSM IRB requires disclosure to the subject about any foreseeable circumstances under which the investigator may be required to disclose protected health information (PHI) to a third party (e.g., mandatory reporting of infectious diseases, mandatory reporting of suspected child abuse, etc.).

4. In addition, UTGSM IRB will review questionnaires, data collection tools, surveys and other methods used in the study to collect information to determine the type and means of obtaining information from and about subjects.

5. UTGSM IRB may require researchers to obtain a certificate of confidentiality should the study involve the collection of information about sensitive, stigmatizing or illegal activities. Certificates of confidentiality ensure that investigators cannot be compelled to disclose confidential research data under legal compulsion. "Sensitive" research includes, but is not limited to, the collection of information falling into any of the following categories:
    a. Information relating to sexual attitudes, preferences or practices;
    b. Information relating to the use of alcohol, drugs or other addictive products;
    c. Information pertaining to illegal conduct;
    d. Information that if released could reasonably be damaging to an individual's financial standing, employability, or reputation within the community;
    e. Information that would normally be recorded in a patient's medical record and the disclosure of which could reasonably lead to social stigmatization or discrimination;
    f. Information pertaining to an individual's psychological well-being or mental health; and
    g. Information pertaining to the diagnosis and/or treatment of communicable diseases.

6. Investigators must request a certificate of confidentiality from the appropriate federal official. For research involving mental disorders or substance abuse, they must contact the National Institute on Alcohol Abuse and Alcoholism, the National Institute on Drug Abuse or the National Institute of Mental Health. The Assistant Secretary of Health issues certificates of confidentiality for biomedical, behavioral, clinical, or other research that does not fall into these categories.

7. Investigators will be asked to supply UTGSM IRB with a copy of any Certificate of Confidentiality obtained.

8. The confidentiality of research subjects shall also be maintained when any study information is kept by recorded means such as audio or videotapes. The investigator is required to tell the subject how his/her identity will be or will not be disclosed in these instances, when the tapes may be used for other

broadcasts or educational purposes, and when such recorded information shall be accessed, stored and /or destroyed.

9. Live case recording or broadcast (including photography) of clinical research must have prior IRB approval. In all events, the research consent will be modified to contain additional language regarding the taping/ photography, any additional risks to the subject due to the taping / live broadcast (such as increased procedure time, increased anesthesia time, loss of confidentiality, etc.).

10. Any communications between the study site and the IRB concerning specific research subjects will identify the subject by study number or initials.

11. If a subject calls or writes the IRB, their identity will be referenced by study number or initials in all communications presented to the Board for review.