UNIVERSITY OF TENNESSEE COLLEGE OF MEDICINE CHATTANOOGA INSTITUTIONAL REVIEW BOARD RESPONSIBILITIES OF INVESTIGATORS

I. PURPOSE

To document the responsibilities of investigators who submit study applications to the University of Tennessee College of Medicine Chattanooga Institutional Review Board.

II. SCOPE

This SOP applies to investigators.

Personnel Responsible:

UTCOMC IRB administrative staff, IRB members and investigators.

III. BACKGROUND

Protection for the rights and welfare of human subjects is achieved through a framework of comprehensive rules and regulations, independent oversight of research activities by IRBs and other responsible agencies, and the moral integrity and conscientiousness of individual investigators. In submitting a new study application for review and approval by the UTCOMC IRB, the principal investigator agrees to assume important responsibilities related to the protection of human subjects. These obligations involve adhering to the approved protocol, securing and documenting informed consent, obtaining prior IRB approval for revisions, reporting in a timely fashion on the progress of the research, notifying the IRB regarding unanticipated problems and serious or continuing noncompliance with regulations and policies, reporting on the completion of the study, maintaining complete study records, supervising all key research personnel and assuring their basic training in the protection of human subjects, disclosing potential conflicts of interest, and permitting inspection of all study records. In order to fulfill these obligations, investigators must execute them in accord with applicable law, regulations, and local IRB policies and procedures. Because investigators and other key research personnel are the individuals who interact directly with human subjects, their fulfillment of these obligations is crucial to effective protection for the rights and welfare of human subjects.

In accordance with:

45 CFR 46; 21 CFR11, 50, 54, 56, 312, and 812

OHRP Investigator Responsibilities Frequently Asked Questions
http://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/investigator-responsibilities/

Guidance for Industry: Investigator Responsibilities - Protecting the Rights, Safety, and Welfare of Study Subjects (October 2009)
www.fda.gov/downloads/Drugs/.../Guidances/UCM187772.pdf

Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy and Security Rules
https://www.hhs.gov/sites/default/files/privacysummary.pdf

UTCOMC Research Data Management (Retention and Ownership) Policy https://www.UTCOMC.edu/research/about/reports-and-publications/index.php

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

IV. PROCEDURES

1. Principal investigators (PIs) and Co-PIs must include in their initial study application, *UTCOMC IRB: Study/Project Smart Form Application, Form c: Revision/Change Form d: Continuing Review* to the UTCOMC IRB a signed statement that they agree to assume the following responsibilities and to faithfully execute them in accord with applicable federal regulations for the protection of human subjects and UTCOMC IRB policies and procedures:
   - I certify that the information provided in this application is complete and correct to the best of my knowledge.
   - I accept ultimate responsibility for the conduct of this study, the ethical performance of the project, and the protection of the rights and welfare of the human subjects who are directly or indirectly involved in this project.
   - I will comply with all policies and guidelines of the UTCOMC and affiliated institutions where this study will be conducted, as well as with all applicable federal, state and local laws regarding the protection of human subjects in research.
   - I understand that any false, fictitious or fraudulent statements or claims may result in criminal, civil or administrative penalties.
   - I will ensure that personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the IRB-approved protocol.

- I will not modify this IRB-approved protocol or any attached materials without first obtaining IRB approval for an amendment to the previously approved protocol.
- I assure that the protected health information requested, if any, is the minimum necessary to meet the research objectives.
- I assure that the protected health information I obtain, if any, as part of this research will not be reused or disclosed to any parties other than those described in the IRB-approved protocol, except as required by law.
- I assure that adequate resources to protect participants (i.e., personnel, funding, time, equipment and space) are in place before implementing the research project, and that the research will stop if adequate resources become unavailable

2. In order to adequately fulfill these obligations, investigators and other key research personnel must observe federal regulations, guidance, and local IRB policies and procedures that relate to their implementation. Lack of knowledge regarding relevant policies and procedures does not excuse failure to meet these obligations.

3. The IRB has the authority to suspend or terminate the privilege of investigators to conduct a study due to any instance of serious or continuing noncompliance with the obligations stated above and the policies and procedures for their implementation.

4. A copy of the signed statement of investigators and all communications regarding their fulfillment of these obligations will be maintained in the IRB electronic file for the study.