

**UNIVERSITY OF TENNESSEE HEALTH SCIENCE CENTER
INSTITUTIONAL REVIEW BOARD
RESPONSIBILITIES OF INVESTIGATORS**

I. PURPOSE

To document the responsibilities of investigators who submit study applications to the University of Tennessee Health Science Center Institutional Review Board.

II. SCOPE

This SOP applies to investigators.

Personnel Responsible:

UTHSC 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 UTHSC 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:

45CFR46; 21CFR50, 56

OHRP Investigator Responsibilities Frequently Asked Questions, located at <http://www.hhs.gov/ohrp/investigatefaq.html>

FDA Draft Guidance for Industry: Protecting the Rights, Safety, and Welfare of Study Subjects – Supervisory Responsibilities of Investigators, located at <http://www.fda.gov/OHRMS/DOCKETS/98fr/07d-0173-gdl0001.pdf>

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

IV. PROCEDURES

1. Principal investigators must include in their initial study application to the UTHSC 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 UTHSC IRB policies and procedures:
 - a. To conduct the research according to the IRB-approved protocol;
 - b. To obtain and document the informed consent and/or assent of subjects or subjects' legally authorized representatives, using the UTHSC IRB-approved informed consent process and documents, prior to the subjects' participation in any research procedures, unless these requirements have been altered or waived by the IRB;
 - c. To obtain prior approval from the IRB for any modifications of previously approved research, including modifications to the informed consent process and documents, except those necessary to eliminate apparent immediate hazards to subjects;
 - d. To ensure that progress reports and requests for continuing review and approval are submitted in the time frame and the manner prescribed by the IRB, but no less than once per year;
 - e. To provide the IRB with prompt reports of any unanticipated problems involving risks to subjects or others, including adverse events and protocol deviations;
 - f. To provide the IRB with prompt reports of serious or continuing noncompliance with the federal regulations for the protection of human subjects or the requirements or determinations of the IRB;
 - g. To notify the IRB regarding the completion of the study;
 - h. To maintain all study records for a period of six years, including all correspondence with the IRB and other entities involved in conducting and supporting the research;
 - i. To assure that all collaborating investigators and other key research personnel involved in the research study are fully informed regarding: (i) the study procedures; (ii) informed consent requirements; (iii) the potential adverse events associated with study participation and the steps necessary

- to minimize potential risks; (iv) reporting requirements for unanticipated problems; and (e) data collection and record-keeping requirements;
 - j. To assure that all key research personnel complete required training regarding the protection of human subjects prior to their initiation of study activities;
 - k. To disclose to the IRB all conflicts of interest as defined in institutional policy that may relate to the conduct of the research; and
 - l. To permit inspection and audit of all records related to the conduct of the study by authorized representatives of the IRB and departments or agencies supporting or conducting the research.
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 file for the study.