

**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:

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>

UTHSC Research Data Management (Retention and Ownership) Policy

<https://www.uthsc.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, *UTHSC IRB Form 1: Study/Project Application, Form 2: Change Request & Amendments, Form 3: Continuing Review, and PI Response Forms* 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 collect, where possible, information regarding the gender and racial/ethnic origin of all subjects, and to report this information to the IRB as requested;
- h. To notify the IRB regarding the completion of the study;
- i. To retain study/project records according to the applicable regulation or if more than one regulation applies, the longest applicable period:
 - i. **OHRP Requirements:** For all research that is regulated by HHS and reviewed under 45 CFR 46, records relating to the research must be retained for a least three years after the completion of the research, including consent forms and all correspondence with the IRB and other entities involved in conducting and supporting the research;
 - ii. **FDA Requirements:** An investigator conducting research that is regulated by the FDA and involves drugs or biologics being tested in humans must retain the research records for a period of 2 years following the date a marketing application is approved for the drug for the indication for which it is being investigated or, if no application is being filed or the application is not approved for such indication, until 2 years after the investigation is discontinued and the FDA is notified.

An investigator conducting research that involves a medical device shall maintain the research records for a period of 2 years after the later of the following two dates: (i) the date on which the investigation is terminated or completed; or (ii) the date that the records are no longer required for purposes of supporting a premarket approval application or a notice of completion of a product development protocol.

- iii. **HIPAA Requirements:** Research that involves collection of protected health information (PHI) is subject to the HIPAA regulations. Research records including signed consent forms that contain the HIPAA authorization must be retained for six years after the date on which the subject signed the consent form or the date when it was last in effect, whichever is later;
- iv. **University Requirements:** The University of Tennessee Health Science Center (UTHSC) requires research records to be retained for a minimum of 5 years following the conclusion of the research project.
- v. **Sponsor Requirements:** If a research project is sponsored, then the investigator must comply with the terms for record retention outlined in the contract with the sponsor.
- vi. **Questions of data validity:** If there are questions or allegations about the validity of the data or appropriate conduct of the research, the

investigator must retain all the original research data until such time as the questions or allegations have been completely resolved.

- j. 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;
 - k. To assure that all key research personnel personally complete required training regarding the protection of human subjects prior to their initiation of study activities;
 - l. To disclose to the IRB all conflicts of interest as defined in institutional policy that may relate to the conduct of the research; and
 - m. 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 electronic file for the study.