

**UNIVERSITY OF TENNESSEE GRADUATE SCHOOL OF MEDICINE  
INSTITUTIONAL REVIEW BOARD  
RESPONSIBILITIES OF INVESTIGATORS**

**I. PURPOSE**

To document the procedures for submissions to the University of Tennessee Graduate School of Medicine Institutional Review Board (UTGSM IRB) by investigators

**II. SCOPE**

This SOP applies to the IRB administrative staff, IRB members, investigators and sponsors.

**Personnel Responsible:**

UTGSM IRB administrative staff 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.

**REFERENCES**

**45 CFR 46, 21 CFR 11, 50, 54, 56, 312, and 812**

OHRP Investigator Responsibilities Frequently Asked Questions  
<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/investigator-responsibilities/index.html>

Guidance for Industry: Investigator Responsibilities - Protecting the Rights, Safety, and Welfare of Study Subjects (October 2009)

[www.fda.gov/downloads/Drugs/.../Guidances/UCM187772.pdf](http://www.fda.gov/downloads/Drugs/.../Guidances/UCM187772.pdf)

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

#### **IV BIOETHICS TRAINING**

Consistent with the University's commitment to the ethical conduct of research, investigators governed by these regulations are required to complete an [on-line instructional program](#) covering issues which affect the ethics of research involving human subjects. Completion of the course is documented by an on-line multiple-choice test. A passing grade of 80 is required for certification of course completion. Re-certification is required every 3 years.

No proposed research will be reviewed by the IRB until the investigator has completed the course(s). Investigator, co-investigators, coordinators, or people conducting consent must take the course. Residents, Fellows or any Trainee of any discipline who are submitting Case Reports must complete the CITI course.

The CITI program will automatically notify the IRB when a course is completed and the information will be automatically uploaded into iMedRIS, the IRBs electronic system.

#### **V PROCEDURES**

Principal investigators (PIs) and Co-PIs must include in their Initial Study Application, Change Request & Amendments, Continuing Review Submission Form, and PI Response Forms to the UTGSM 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 UTGSM 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 UTGSM 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;

1. Following approval, the investigator is required to provide to the board within the time frames set by the IRB the following for review:
  - a. Amendments or changes in the protocol or informed consent disclosure; approval of all revisions must be obtained from the board prior to initiation unless necessary to eliminate immediate hazards to the subjects;
  - b. Any protocol waivers or deviations with the investigator's action plan for avoiding recurrence, if applicable;
  - c. FDA 483 Warning Letters or other correspondence;
  - d. Any other audit report by a regulatory agency, sponsor or IRB;
  - e. Any unanticipated, serious adverse reactions or other unanticipated problems involving risks to the subject or others, and thought to be related to study procedures: (see SOP 17)

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 maintain all study records for a period of three years after the completion of the study, including consent forms and all correspondence with the IRB and other entities involved in conducting and supporting the research;

j. To maintain all consent forms for a period of six years after the date on which the subject signed the consent form containing a HIPAA authorization or the date when it was last in effect, whichever is later;

k. For all drug studies with an IND, to maintain all study records for a period of two 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 to be filed or if the application is not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified;

l. For all FDA-regulated device studies, to maintain the records for a period of 2 years after the latter of the following two dates: The date on which the device investigation is terminated or completed, or the date that the records are no longer required for purposes of supporting a device premarket approval application or a notice of completion of a product development protocol.

m. 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;

n. To assure that all key research personnel personally complete required training regarding the protection of human subjects prior to their initiation of study activities;

- o. To disclose to the IRB all conflicts of interest as defined in institutional policy that may relate to the conduct of the research; and
- p. 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 system, iMedRIRS for the study.