UNIVERSITY OF TENNESSEE GRADUATE SCHOOL OF MEDICINE
INSTITUTIONAL REVIEW BOARD
REVIEW OF EXTERNAL REPORTS

I. PURPOSE

To document the procedures for submission and review of Safety Alerts, Unanticipated Problems, and other event reports for a clinical trial.

II. SCOPE

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

Personnel Responsible:

University of Tennessee Graduate School of Medicine Institutional Review Board (UTGSM IRB) members, investigators and sponsors

III. BACKGROUND

During the course of a study, the IRB may receive reports of Unanticipated Problems, DSMB interim analyses, reports of problems involving risks to the subject or others, or other adverse event reports from the sponsor. UTGSM IRB reviews such reports as the study progresses to ensure that the risk/benefit ratio relationship of the research remains acceptable. UTGSM IRB will review these submissions to determine their impact on continuation of the research, whether the informed consent disclosure requires revision, and whether subjects who are already enrolled in the study need to be apprised of the new information in order to determine their willingness to continue participation.

In Accordance With:

45 CFR 46; 21 CFR 56

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

IV. PROCEDURES

1. Studies conducted under an IND / IDE: Serious adverse events that have been deemed as unanticipated problems by a Central Monitoring Agency (IND Safety Reports and unexpected adverse device effects (UADEs) must be reported by the investigators to the UTGSM IRB within 10 days of receipt by the research site. These reports must contain the sponsor's analysis of the event(s).

2. Other reports from outside agencies related to safety or risk information regarding a particular study should be submitted to the IRB within 10 days of receipt only when the investigator has determined the reports affect risk / benefit for subjects in the study. These should be submitted along with a summary of the investigator's assessment of the impact on the risk / benefit to the subjects.

3. The IRB Chairman will review the submitted documents and present them at a meeting of the full Board to determine if:
   a. new or unanticipated risks should be added to the informed consent disclosure;
   b. the risk / benefit ratio for the study has changed and/or the review period for the study need to be altered;
   c. there additional safety concerns

5. The IRB staff will inform the investigator of its review and any required modifications in the consent or reporting requirements.