

**UNIVERSITY OF TENNESSEE HEALTH SCIENCE CENTER
INSTITUTIONAL REVIEW BOARD
REVIEW OF PROGRESS AND SAFETY REPORTS, OTHER THAN REPORTS
OF UNANTICIPATED PROBLEMS**

I. PURPOSE

To document requirements and procedures for submission to the IRB of safety and progress reports for research studies, other than reports of unanticipated problems.

II. SCOPE

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

Personnel Responsible:

Institutional Review Board members, investigators and sponsors.

III. BACKGROUND

HHS and FDA regulations for the protection of human subjects require that IRBs maintain procedures for continuing assessment of the acceptability of previously approved studies. This process includes review of the risks of study participation, the potential benefits, the informed consent process and appropriate additional safeguards necessary to protect subjects. In particular, the IRB must determine whether any new information has emerged that would alter the acceptability of the risk-benefit ratio for the study, change the procedures necessary to protect the welfare of subjects, or necessitate revision of the informed consent process/documents.

Reports regarding the progress of research studies and the safety of research interventions, other than reports of unanticipated problems, are pertinent to these assessments. Reports relevant to the safety of study interventions may be issued by a variety of entities, including the study sponsor, the data monitoring committee (DMC), and the FDA. These reports include FDA Safety Alerts and Public Health Advisories, and DMC reports on the safety of study interventions. Similarly, reports on the overall progress of research studies may be developed, including reports of interim analyses by the DMC and annual reports of the sponsor of the research.

It is important that the IRB review these various reports in a timely fashion to assure that its judgments regarding the acceptability of the risk/benefit ratio, the procedures necessary for protecting the welfare of subjects, and the adequacy of the consent documents/process are based on complete, accurate and current information.

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. The principal investigator shall forward all safety and progress reports (other than reports of unanticipated problems) supplied by the sponsor to the IRB within 10 working days of their receipt by the principal investigator. Reports to be submitted include, but are not limited to, the following:
 - a. FDA Safety Alerts
 - b. FDA Public Health Advisories
 - c. DMC reports
 - d. Sponsor interim or annual reportsReports of unanticipated problems, including adverse events, should be submitted in accord with UTHSC IRB SOP: Reporting Unanticipated Problems, including Adverse Events.
2. The principal investigator will review each report and provide the IRB with his or her assessment of whether any changes in the risk-benefit ratio for the study, study procedures, or the informed consent document/process are necessitated based on the report being submitted.
3. The Principal Investigator will use the **Data Safety Monitoring Board/Annual Reports** form within iMedRIS to submit the reports outlined in item #1 for IRB review.
4. The principal investigator will apply his/her electronic signature to the form prior to submission to the IRB.
5. Upon receipt of a progress or safety report, the administrative staff will electronically forward it to a Chair or designee for review. Based on the review, a preliminary determination will be made about whether the report requires a revision of the protocol, the informed consent document/process, or

other aspect of the study, or suspension or termination of the study. If changes are determined to be necessary and represent more than minor revisions, then the changes must be reviewed and approved by the convened IRB.

6. The IRB review of the submitted report may result in any of the following actions:
 - a. stipulation of changes in study procedures and/or the informed consent document/process;
 - b. suspension of some or all study-related procedures pending the completion of IRB review;
 - c. termination of IRB approval based on unacceptable changes in the risk-benefit ratio; or
 - d. requirements for the investigator to submit additional information as deemed appropriate or necessary by the IRB.
7. The IRB will inform the investigator in writing of its review and any required modifications in the study. Modifications to the study must be submitted via Form 2: Change Request & Amendments via iMedRIS. See SOP: Review of Revisions in Approved Studies.
8. A copy of all correspondence/reports will be maintained in the electronic IRB files.
9. Correspondence regarding the progress or safety reports will be placed on the electronic meeting agenda and sent electronically to Board members before the Board meeting each applicable week when the agenda is finalized.
10. A copy of the finalized agenda is provided to the Vice Chancellor for Research in fulfillment of the regulatory requirement to communicate the IRB's findings and actions to the institution in writing (previously found at 45 CFR 103(a)(4)(i), now found at 45 CFR 46.108(a)(3)(i) in the revised Common Rule).