

**UNIVERSITY OF TENNESSEE HEALTH SCIENCE CENTER
INSTITUTIONAL REVIEW BOARD
AUDITING OF RESEARCH STUDIES**

I. PURPOSE

To document the policy and procedures used by the University of Tennessee Health Science Center Institutional Review Board regarding the auditing of IRB-approved studies.

II. SCOPE

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

Personnel Responsible:

UTHSC IRB administrative staff, compliance auditing staff.

III. BACKGROUND

Under federal regulations for the protection of human subjects, IRBs must maintain written procedures for ensuring prompt reporting of any unanticipated problems involving risks to subjects or others, or any serious and continuing noncompliance with federal regulations or local IRB policies and procedures. In addition, the regulations require IRBs to conduct continuing review of previously approved research, and specifically authorize IRBs to observe or have a third party observe the consent process and the research as part of the continuing review process.

One component of the IRB's compliance oversight activities involves auditing of previously approved studies. The process of compliance auditing is meant to accomplish several important purposes. First, it is intended to assure that human subjects are properly protected, and that the procedures used to accomplish this goal are carefully documented. Second, the auditing process is intended to assist investigators in complying with the current regulatory standards for protecting human subjects and in avoiding any external sanctions that may result from non-compliance with the standard of practice. Finally, this process is intended to assure that the University and affiliated institutions remain in good standing with federal agencies having oversight of human subjects research activities.

The purpose of this policy is to provide written guidance on operational requirements for compliance auditing activities.

In Accordance With:

45CFR46.103(b)(5); 45CFR46.109(e); 21CFR56.108(b); 21CFR56.109(f)

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 UTHSC IRB will have the authority or may designate a third party to observe the conduct of any research activity, and may review at any time all research records, including but not limited to informed consent documents, regulatory files, IRB files, subjects' research and medical records, clinical materials, record storage, computer files, and results of procedures and tests performed during the course of the research.
2. Research compliance auditing staff will also have the authority to observe the informed consent process, and to interview subjects either during or after their participation in research activities.
3. The IRB research compliance auditor, at the direction of the Chairman or the full Board, will schedule audits of previously approved research studies.
4. Criteria for choosing studies for audit include, but are not limited to, the following:
 - a. Random selection;
 - b. Sufficient cause as determined by the IRB;
 - c. High risk studies as designated by the Board;
 - d. Any report of suspected noncompliance;
 - e. Research terminated by the IRB due to failure by the investigator to submit the study for continuing review or failure to respond to a request for information from the IRB;
 - f. Verification of continuing review reports; and
 - g. Studies reporting a large number of unanticipated problems, including adverse events and/or protocol deviations;

5. Prior to initiation of an audit, the investigator will be notified by the IRB research compliance auditing staff by fax, email, or certified mail. An acceptable date and time will be identified for the audit.
6. The UTHSC IRB audit form will be used and may be amended to capture all required information.
7. Audit reviews may include:
 - a. any study/research-related documents and source documents, such as medical records;
 - b. specimens and associated collection processes; and
 - c. computer hardware and/or software associated with the research.
8. The principal investigator will be requested to provide a list of all study participants to the auditor.
 - a. If the number of subjects enrolled is large, the auditor will select at random 20-30% of the subject population to be audited. Otherwise, all records will be reviewed.
 - b. In the case of a for cause audit, the IRB may request a 100% audit of study participants' records.
9. A pre-audit interview may be conducted with the investigator or other key research personnel to document the delegation of authority related to the following activities:
 - a. Regulatory affairs/IRB submissions;
 - b. Obtaining of informed consent;
 - c. Recruitment of study participants;
 - d. Reporting of adverse events/protocol deviations;
 - e. Reporting of injury or other unforeseen events to the IRB/sponsor;
 - f. Maintaining study documentation/CRFs;
 - g. Test article accountability;
 - h. Monitoring by the sponsor/CRO; and
 - i. Verification of continuing review reports.
10. A report of audit findings will be prepared and submitted to the IRB chairman for review and action. The Chairman may consult with the full Board regarding corrective action plans necessary to correct deficiencies identified at audit. A copy of the audit report and a letter indicating an necessary corrective actions will be sent to the principal investigator.
11. If the results of the audit identify outstanding issues, a letter outlining the basis for the findings and requesting needed explanations,

corrective action plans and/or study revisions will be sent to the investigator.

12. If preliminary findings so indicate, the IRB may suspend the study enrollment or activities or terminate the study and take appropriate action to ensure the safety and welfare of the subjects.
13. The PI may be required to appear before the full Board or to meet with an IRB-appointed investigative subcommittee to address issues identified at audit. However, the PI may not have attorneys or other witnesses present at the meetings.
14. The IRB may engage any outside consultant or expert as necessary to conduct the audit.
15. If subjects are considered at risk due to the actions of the PI or other key research personnel, appropriate officials of the institution in which the research is occurring and the sponsor of the research will be notified, and appropriate action will be taken to ensure the safety and welfare of the subjects.
16. Audit reports, corrective action plans, and correspondence with investigators will be transmitted to appropriate officials of the institution in which the research is occurring as necessary to assure proper protection for the rights and welfare of human subjects.
17. Copies of audit reports and correspondence will be placed in the study files, as well as being included in the minutes of the next scheduled meeting of the full Board.
18. Follow-up audits will be scheduled when substantial deficiencies have been identified whose correction is crucial in providing adequate protection for the rights and welfare of subjects.