UNIVERSITY OF TENNESSEE COLLEGE OF MEDICINE
INSTITUTIONAL REVIEW BOARD
Auditing of Research Studies

I. PURPOSE

To document the policy and procedures used by the UTCOMC IRB regarding the auditing of IRB-approved studies.

II. SCOPE

This SOP applies to the IRB administrator, IRB members, and investigators

Personnel Responsible

IRB administrator and IRB Members

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:

1. To assure that human subjects are properly protected, and that the procedures used to accomplish this goal are carefully documented;
2. To assist investigators in complying with the current regulatory standards for protecting human subjects and avoid any external sanctions that may result from noncompliance with the standard of practice;
3. To assure that the University and affiliated institutions remain in good standing with federal agencies having oversight of human subjects research activities as well as federal entities and non-governmental institutions that provide financial support for the conduct of research.

In accordance with:

For studies approved under the revised Common Rule:
45 CFR 46.108(a)(4); 45 CFR 46.109(a); 45 CFR 46.109(e); 45 CFR 46.111(a)(6); 45 CFR 46.113; and

For studies approved under the Pre-2018 Common Rule:
45 CFR 46.103(b)(5); and

For FDA-regulated studies:
21 CFR 56.108(b); 21 CFR 56.109(f); 21 CFR 56.111(a)(6)

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 UTCOMC/EHS 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:
   a. Informed consent documents;
   b. Regulatory files;
   c. IRB files;
   d. Subjects' research and medical records;
   e. Clinical materials;
   f. Record storage for investigational articles and specimens;
   g. Computer files;
   h. Transmission of data and specimens to other sites; and
   i. 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. Criteria for choosing studies for audit include, but are not limited to:
   A. **Random/Routine**: The IRB Compliance Advisor randomly selects a previously approved research study for routine audit.
   B. **For-cause:** This review is performed when concerns regarding regulatory compliance, protocol adherence, or subject safety are brought to the attention of the IRB, including:
   i. Any report of suspected non-compliance;

ii. Research terminated by the IRB due to failure of the investigator to submit the study for continuing review or failure to respond to a request for information from the IRB;
iii. Questions regarding the accuracy of continuing review reports;
iv. Studies reporting a large number of unanticipated problems, including adverse events and/or protocol deviations; or
v. Studies designated as high risk by the Board.

C. **Training**: This audit is intended to support new researchers or researchers who initiate projects without external monetary support. The training audit is generally performed shortly after the project receives initial IRB approval and provides instruction on procedures for assuring optimal regulatory compliance.

D. **Investigator-Initiated**: An investigator or research coordinator may request an on-site review to assist in keeping records and procedures in compliance with federal regulations and institutional policies or to prepare for an external audit by a sponsor or federal agency.

E. **Informed Consent**: This audit is intended to support researchers in conducting the informed consent process. It may include observational assessment of consent interviews, evaluation of the training provided to key study personnel obtaining informed consent, review of the completeness of the process of documenting informed consent, and/or review of manner in which informed consent documents are stored.

4. Prior to initiation of an audit, the investigator will be notified by the compliance auditor via IRBNet and/or email regarding the type of audit planned. An acceptable date and time will be determined for the audit.

5. The UTCOMC audit form will be used and may be amended to capture all required information.

6. Audit review may include but are not limited to:
   a. IRBNet documents and correspondence
   b. Any study/research-related documents and source documents, such as medical records;
   c. Specimens and associated collection processes
   d. Test article documentation and storage; and
   e. Computer hardware and/or software associated with the research.

7. 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 may select at random 20-30% of the subject population to be reviewed. 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.

8. 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 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/clinical report forms;
    g. Test article accountability;
    h. Monitoring by the sponsor/clinical research organization; and
    i. Verification of continuing review reports.

9. A report of audit findings will be prepared and submitted to the IRB for review and action, and a copy of the audit report will be sent to the principal investigator.

10. 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.

11. 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.

12. The principal investigator may be required to appear before the full Board or to meet with an IRB-appointed investigative subcommittee to address issues identified by audit. However, the investigator may not have attorneys or other witnesses present at the meetings.

13. The IRB may engage any outside consultant or expert as necessary to conduct the audit.

14. If subjects are considered at risk due to the actions of the investigator 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.

15. 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.

16. Copies of audit reports and correspondence will be placed in the IRBNET study files and kept by the compliance staff.

17. 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.