UNIVERSITY OF TENNESSEE GRADUATE SCHOOL OF MEDICINE
INSTITUTIONAL REVIEW BOARD
AUDITS OF RESEARCH STUDIES

I. PURPOSE

To document the policy and procedures used by University of Tennessee Graduate School of Medicine Institutional Review Board (UTGSM IRB) regarding the audits of IRB sites.

II. SCOPE

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

Personnel Responsible:

UTGSM IRB administrative staff, compliance auditing staff

III. BACKGROUND

It is the policy of UTGSM IRB to protect the integrity of clinical research reviewed by UTGSM IRB by providing oversight of clinical investigations under its review. The purpose of this policy is to provide written guidance on operational requirements for such compliance auditing activities.

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.

In Accordance With:

45CFR46.103(b)(5); 45CFR46.109(a); 45CFR46.109(e); 45CFR 46.111(a)(6); 45 CFR 46.113; 21CFR56.108(b); 21CFR56.109(f); 21CFR56.111(a)(6)

Institutional Review Boards Frequently Asked Questions – Information Sheet http://www.fda.gov/RegulatoryInformation/Guidances/ucm126420.htm

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

IV. PROCEDURES

A. UTGSM IRB will have the authority to observe the implementation of clinical trial activity, and review all trial records, including informed consents, regulatory files, IRB files, subject medical records, research records, clinical trial materials, record storage, computer files, procedure and tests results.

B. The IRB staff will also have the authority to observe the informed consent process, and to interview subjects.

C. The IRB Regulatory Specialist, at the direction of the Chairperson, will schedule audits of clinical trial sites.

D. Primarily there are three types of audits that may be conducted by the UTHSC IRB:
   1. Informed consent audits in which the IRB Regulatory Specialist may observe the consent interview and review the consent forms signed by subjects;
   2. Random routine audits in which the IRB Regulatory Specialist randomly selects previously approved research studies; and
   3. For-cause audits, which are performed when concerns regarding compliance, protocol adherence or subject safety are brought to the attention of the IRB. These audits are performed at the direction of the Chair, Director or the full Board.

E. Audit selection criteria includes, but is not limited to, audits done:
   1. At random
   2. At the direction of the IRB for any cause
   3. For high risk studies as designated by the Board
   4. Upon report of suspected noncompliance
   5. Research terminated by the IRB due to failure by the investigator to submit a study for continuing review or failure to respond to a request for information from the IRB
   6. To verify continuing review reports
   7. For studies reporting a large number (as determined by the IRB) of SAEs or protocol deviations

F. When a compliance audit is initiated, the investigator will be notified by the IRB staff (by phone, fax, email, or certified mail). A mutual date and time will be decided upon for the audit.

G. The UTGSM IRB audit form will be used and may be amended to capture all required information.

H. Documents that may be selected for review include, but are not limited to:
    1. Regulatory submissions and associated IRB correspondence
    2. Changes in the protocol and associated IRB correspondence
    3. Review of any lapses in IRB approvals
    4. Review of eligibility criteria
    5. Review of all informed consents
    6. Review of subject accrual and recruitment practices
    7. Review of data collection tools and procedures
    8. Review of adverse event reporting (including timeliness of reports to the IRB, Sponsor and other regulatory agency.
    9. Review of protocol deviations (including timeliness of reports to the IRB, Sponsor and other regulatory bodies)
    10. Review of continuing review reports
    11. Site of test article storage
    12. Test article accountability
    13. Review of any procedures for the collection and use of stored specimens/tissues. Review will include specimen collection, location, labeling, tracking, access, analysis, distribution, confidentiality, storage, security, use, and disposal.

I. The principal investigator or study coordinator will be requested to provide a list of all study participants to the auditor (identifying subjects by code or study number only).
    1. If the number of subjects enrolled is large, the auditor will select at random 20-30% of the population to be audited. Otherwise, all records will be reviewed.
    2. In the case of a for cause audit, the IRB may request a 100% audit of study participant's records.

J. A pre-audit interview may be conducted with the investigator or staff to document the delegation of authority related to the following activities:
    1. Regulatory affairs / IRB Submissions
    2. Obtaining of informed consent
    3. Recruitment of study participants
    4. Reporting of adverse events/ protocol violations / deviations
    5. Reporting of injury or other unforeseen event to the IRB / Sponsor
    6. Maintaining study documentation / CRFs
    7. Test article accountability
    8. Subject accrual
    9. Monitoring by the Sponsor / CRO
    10. Verification of continuing review reports

K. If the results of the audit identify outstanding issues, a letter outlining the basis for the findings and the request for needed explanations, corrective action plans and study revisions will be sent to the investigator. The investigator will be instructed to submit a plan of corrective action by a certain date.

L. The audit report will be submitted to the Chair for review. The audit and investigator's corrective plan of action will be placed on the next agenda for review by the full Board. The Board can either accept the corrective action plan or can require additional corrective measures

M. 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.

N. 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.

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

P. 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.

Q. Copies of audit correspondence and reports will be filed in the IRB office.

R. Follow-up audits will be scheduled when deficiencies have been identified whose correction is substantially important in providing adequate protection for the rights and welfare of subjects.