

20. Audit Procedures

20.1. Policy

The Institutional Review Board (IRB) has the responsibility and authority to observe ongoing research projects and the consent process, as well as conduct continuing review of the project, including audits of research records. The IRB, through the Research Compliance Office (RCO), will audit research records randomly, for cause, and based on the compliance records of the investigators. Full cooperation by the responsible principal investigator and other members of the research team (if necessary) is expected.

On-site audits are conducted as part of the Human Research Protection Program's (HRPP) continuing compliance oversight in accordance to Federal regulations. The purpose of the audit procedure is to ensure protection of the human subjects participating in research. The information gathered during the audit is for the IRB to use to monitor the implementation of approved protocols, identify areas that need improvement, correction or targeted education, and to gather information for continuous improvement on ways to improve the audit tool or the audit process. Investigators are notified, generally by e-mail, at least 2-5 days prior to the conduct of the audit.

20.1.1. Who Can Perform an Audit?

- Federal agency overseeing the research (Food and Drug Administration (FDA), Office for Human Research Protection (OHRP), etc.)
- Research study sponsor (pharmaceutical company, funding agency, etc.)
- Institutional Review Board (IRB Chair, IRB member, IRB staff, etc.)

20.1.2. Federal Oversight

OHRP conducts compliance audits and provides information about these compliance activities on their web site. Information available includes an overview, compliance procedures, and common compliance oversight findings. OHRP also makes available compliance determination letters sent from OHRP to the audited institution or University.

The FDA also conducts inspections of IRBs and investigators. The FDA makes available warning letters sent from the FDA to inspected entities on their web site.

This information can be useful in evaluating specific protocols in terms of methodology and/or decision making and to the IRB in determining and following policies and guidelines.

20.2. Procedures

The UMKC IRB, and administrative staff, have the authority or may designate a third party to:

- Observe the conduct of any research activity,
- May review at any time all research records, including but not limited to 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,

- Observe the consent process, and
- Interview subjects either during or after their participation in research activities.

The IRB administrative staff will schedule audits of previously approved research studies.

Criteria for choosing studies for audit include, but are not limited to, the following:

- Random selection;
- Sufficient cause as determined by the IRB;
- High risk studies as designated by the IRB;
- Any report of suspected noncompliance;
- 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;
- Verification of continuing review reports; and
- Studies reporting a large number of Unanticipated Problems, including Adverse Events and/or protocol deviations.

Prior to initiation of an audit, the investigator will be notified by the IRB staff. An acceptable date and time will be identified for the audit.

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

Audit reviews may include:

- Any study/research-related documents and source documents, such as medical records or data collection sheet(s);
- Specimens and associated collection processes; and
- Computer hardware and/or software associated with the research.

The principal investigator will be requested to provide a list of all study participants to the auditor.

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.

In the case of a for cause audit, the IRB may request a 100% audit of study participants' records.

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:

- Regulatory affairs/IRB submissions;
- Obtaining of consent;

- Recruitment of study participants;
- Reporting of Adverse Events/protocol deviations;
- Reporting of injury or other unforeseen events to the IRB/sponsor;
- Maintaining study documentation/CRFs;
- Test article accountability;
- Monitoring by the sponsor/CRO; and
- Verification of continuing review reports.

A report of non-exempt audit findings will be prepared and submitted to the IRB Chair for review and action. The Chair 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 any necessary corrective actions will be sent to the PI, PIs department Chair, and Dean.

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 PI, PIs Department Chair, and Dean.

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.

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.

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

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.

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.

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.

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.



Approved by: Lawrence Dreyfus, PhD
Name of University Institutional Official

Signature of University Institutional Official Date