



## **I. Policy**

### **A. Introduction**

The MUSC University Compliance Office conducts audits on research projects involving human participants.

### **B. MUSC Policy**

Audits are a tool to assist the Medical University in achieving compliance with applicable federal regulations and laws and MUSC policy and procedures during the conduct of research involving human participants. This mechanism of post-review monitoring also serves as a vehicle for continuing education, increased operational awareness and quality improvement. Audits consist of record review of both the Institutional Review Board (IRB) and the applicable Principal Investigator's HR study files.

## **II. Procedures**

**A.** The University Compliance Office initiates audits based on the following criteria:

1. **Priority 1: For-Cause-Audit:** Study where allegations of human participants' violations have been lodged against a Principal Investigator.
2. **Priority 2: Administrative Audit:** Study where the IRB Chair has identified a potential administrative problem with study documentation.
3. **Priority 3: Random Audit:** Study randomly selected. Each study has an equal chance of selection.

**B.** The University Compliance Office maintains files to document the selection of studies involving human participants for audit.

**C.** Once a study has been selected for audit, the University Compliance Officer will assign the audit to the appropriate Compliance Auditor with the Compliance Auditor conducting the highest priority audit first.

- D.** Compliance Auditors will use IRB approved checklists as guidance to conduct the audit.
- E.** Once a study is assigned for audit, the Compliance Auditor will prepare a written audit report and forward to the IRB Program Manager for a response. The IRB Program Manager will provide a written response on audit findings within a timely manner and forward to the University Compliance Officer who will review the audit report and response. The University Compliance Officer will approve and/or return the report to the IRB Manager if any additional action or information is needed to resolve any finding(s). Upon approved by the University Compliance Officer, a copy of the audit report and response will be filed in the University Compliance Office.
- F.** The Compliance Auditor will contact the Principal Investigator by phone or e-mail to schedule the audit. Once the audit is scheduled, the Compliance Auditor will confirm the time, date, and place of the audit and provide the Principal Investigator a copy of the checklist used to conduct the audit.
- G.** The Principal Investigator and/or the Study Coordinator will:
  - 1. Provide the following study files for the auditor's review.
    - a) All study related regulatory documents
    - b) Research Participant Screening/Enrollment log (as appropriate)
    - c) Case Report Forms
    - d) Case Report Forms source documents
    - e) Informed Consents and HIPAA for all enrolled/screened subjects
    - f) Study drug and drug accountability logs (as applicable)
    - g) Device accountability logs (as applicable)
    - h) Lab logs (as applicable)
    - i) Other documents/files supporting the conduct of the study.
  - 2. The Principal Investigator and/or Study Coordinator will arrange for a private work area for the conduct of the audit.
- H.** The Compliance Auditor reviews all pertinent study documents and records and completes the checklist to document the audit finding(s).

- I. The Compliance Auditor keeps the Principal Investigator and/or Study Coordinator informed of the progress of the audit. The Compliance Auditor *informally* debriefs the Principal Investigator and/or Study Coordinator at the completion of the audit.
- J. After completion of the audit, the Compliance Auditor prepares a final audit report that is forwarded directly to the University Compliance Officer.
- K. The University Compliance Officer reviews the audit report and adds comments as appropriate. The approved audit report is then forwarded to the Principal Investigator for a response. The Principal Investigator's response includes a correction action plan to reflect the audit findings. Once the Principal Investigator has completed the response, the report should be uploaded into the eIRB system for review by the IRB. The Compliance Auditor will review the Principal Investigator's response and communicate any concerns or correction, if needed, with the IRB Administrator. Once the audit report and response have been appropriately reviewed the audit response is forwarded to the appropriate IRB Chair for information and/or action. A copy of the audit report, Principal Investigator's response, and IRB determination is stored in the eIRB system under Reportable Events.
- L. If so warranted, the IRB Chair/IRB Office may take immediate action to prevent any further enrollment in the study until the audit report is reviewed by the full IRB.
- M. The IRB Chair will present the audit report and Principal Investigator response at the next scheduled IRB meeting.
  - 1. The eIRB system will send reportable event notifications for Principal Investigator submissions and IRB acknowledgments of internal audits to the Compliance Auditor. The IRB Office will keep the University Compliance Office informed regarding the progress of all assigned action(s) until all action(s) are resolved to the satisfaction of the IRB.
- N. The University Compliance Office will document the conduct of audits from initiation to resolution of audit finding(s) on the Audit Status Report.

### III. References

- A. Audit Checklist <http://horseshoe.musc.edu/everyone/compliance/univ-compliance/policies>