Policy Name: **Human Research Audit Policy and Procedures**			
Approved			**Date: 11/01/08**
Effective Date: 02/20/09	**Page 1 of 4**	**Section: HRPP 10.1**	**Policy Number: N/A**
Replaces Policy: N/A			**Dated: N/A**

I. POLICY

A. Introduction

MUSC University Compliance Office will conduct audits on research projects that involve human subjects.

B. MUSC Policy

The audit is a tool to assist the Medical University in achieving compliance with all applicable federal regulations and laws and MUSC policy and procedures in the conduct of human research. Audits will consist of record review of both the Institutional Review Board (IRB) and the Principal Investigator's HR study files.

II. PROCEDURES

A. The University Compliance Office will initiate audits based on the following criteria:

1. Priority 1: For-Cause-Audit: HR study where allegations of human subjects' violations have been lodged against a Principal Investigator.

2. Priority 2: Administrative Audit: HR study where the IRB Chair has identified a potential administrative problem with study documentation.

3. Priority 3: Random Audit: HR study randomly selected using a random number generator. Each study has an equal chance of selection.

B. The University Compliance Office will maintain files to document the selection of HR studies for audit.

C. Once a HR study has been selected for audit, the University Compliance Officer will assign the study to the appropriate Compliance Auditor, with the Compliance Auditor conducting the highest priority audit first. Refer to priorities in paragraph 1 above.

D. Compliance Auditors will use the MUSC and VA Study Audit Checklist and the MUSC IRB Record Review Checklist as guidance to conduct the audit.

E. Once a HR study is assigned for audit, the Compliance Auditor will contact the IRB Program Manager or the appropriate IRB Administrator to gain access to the IRB HR study file. The Compliance Auditor will review the study file and Xerox copies as necessary in the Office of Research Integrity. While reviewing the study file, the Compliance Auditor will complete the MUSC IRB Record Review Checklist. Prior to contacting the Principal Investigator, the study file review should be completed and any questions related to the study addressed by the IRB Office or University Compliance Officer as necessary. Upon completion of the review the Compliance Auditor will return the study file to the IRB Program Manager or IRB Administrator.

F. Upon completion of the MUSC IRB Record Review Checklist, the Compliance Auditor will prepare a written audit report and forward to the IRB Program Manager. The IRB Program Manager will comment on audit findings and forward to the University Compliance Officer who will review the audit report and comments. The University Compliance Officer will approve and/or return the report to the IRB Administrator if any additional action or information is needed to resolve any finding(s). Upon approval by the University Compliance Officer, a copy of the audit report with comments will be filed in the University Compliance Office.

G. The Compliance Auditor will contact the Principal Investigator by phone or e-mail to schedule the audit. In most instances, the Principal Investigator will have no more than ten working days to prepare for and schedule the start of the audit. Once the audit is scheduled, the Compliance Auditor will confirm in writing the time, date, and place of the audit and provide the Principal Investigator a copy of the MUSC and VA Audit Checklist.

H. 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 Subject Screening/Enrollment log (as appropriate)

    c) Case Report Forms

    d) Case Report Forms source documents

    e) Informed Consents and HIPPA 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 that support the study administration

2. Additionally, the Principal Investigator and/or Study Coordinator will arrange for a private work area for the conduct of the audit.

I. The Compliance Auditor will review all pertinent study documents and records and will complete a MUSC and VA Study Audit Checklist to document the audit finding(s).

J. The Compliance Auditor will keep the Principal Investigator and/or Study Coordinator informed of the progress of the audit. If possible, the Compliance Auditor will *informally* debrief the Principal Investigator and/or Study Coordinator at the completion of the audit.

K. After completion of the audit, the Compliance Auditor will prepare a final HR Audit Report. The audit report will be forwarded directly to the University Compliance Officer.

L. The University Compliance Officer will review the audit report; add comments as appropriate. The approved audit report will be forwarded to the Principal Investigator for comments. Once the audit report and Principal Investigator's comments are returned to the University Compliance Office, a copy of the audit report and comments will be forwarded to the appropriate IRB Chair for information and/or action and a copy filed in the University Compliance Office files.

M. The IRB Chair/IRB Office will:

1. If the finding(s) warrant, take immediate action to prevent any further enrollment in the study until the audit report is reviewed by the full IRB.

2. The IRB Chair will present the HR Audit Report at the next scheduled IRB meeting.

3. Within 10 working business days of the IRB meeting, the IRB Office will notify the University Compliance Office of the IRB's acceptance of the audit report finding(s) or of any action(s) initiated in response to the audit finding(s).

4. 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 HR Audit Status Report.

III. REFERENCES