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| Policy/Procedure Title | Study Auditing   |
| Version                | 1                |
| Version Date           | November 7, 2011 |
| Effective Date         | December 1, 2011 |

**PURPOSE**

To define circumstances where human subject research activities may be audited by the CAMC/WVU-Charleston Division IRB and/or the Office of Research and Grants Administration. To define the process by which auditing activities will be conducted.

**POLICY**

To ensure the understanding by investigators, sponsors, study staff, etc. of the auditing possibilities, steps and expectations of the CAMC/WVU-Charleston Division IRB.

**SCOPE**

This policy covers all human subject research that is conducted under any CAMC Health Systems, Inc. facility, involving any CAMC Health Systems, Inc. patient, or under any agreement in place for review by the CAMC/WVU-Charleston Division IRB (IRB).

**DEFINITIONS**

Auditing: A systematic process of objectively reviewing, obtaining information and evaluating data to ascertain the degree of proper documentation and processes established through federal regulations, state regulations and institutional requirements.

For Cause Audit: An audit scheduled due to reported and/or suspected non-compliance.

Routine Audit: An audit scheduled randomly to review for any potential non-compliance.

Pre-Audit: The time between the notification of the upcoming audit and time of the audit.

**RESPONSIBILITY**

**PRINCIPAL INVESTIGATOR**

Principal Investigators must take responsibility for the following prior to the conduct of the audit:

- Be available for a pre-audit meeting as scheduled
- Be available for questions throughout the audit process
- Make adequate space available to conduct the audit
- Ensure all documents are prepared for and provided to the auditors prior to the scheduled audit

**CAMC/WVU-CHARLESTON INSTITUTIONAL REVIEW BOARD**

The IRB will determine studies to be audited. The IRB will instruct the Office of Research and Grants Administration which studies to audit and the time frame for completion of the audit. The IRB will appoint Board members, as necessary, to assist with the audit scheduling, set up and process. Any member appointed must attend the pre-audit meeting and be available throughout the audit process for questions or problems.

## OFFICE OF RESEARCH AND GRANTS ADMINISTRATION STAFF

The Office of Research and Grants Administration Staff (IRB Staff) will schedule and conduct audits at the direction of the IRB. The IRB Staff will contact Principal Investigators to schedule appointed audits. The IRB Staff will prepare final reports for all audits to be presented to the IRB at the next scheduled meeting. Audit reports and IRB audit decisions will be provided to the Vice President of WVU-Charleston Division and the President of the CAMC Health Education and Research Institute.

## PROCEDURES

### Notification of Impending Audit

Upon direction of the IRB, the IRB Staff will notify the Principal Investigator and lead study staff of the upcoming audit of their study. Initial contact could be made through email, phone call and/or letter. IRB Staff will work the Principal Investigator to set a date and time for the audit within a reasonable time frame.

### Pre-Audit Meeting

The IRB Staff will meet with the Principal Investigator on the set date and time to begin the audit process. This pre-audit meeting will be an opportunity for questions to be asked of the IRB Staff and all paperwork to be presented for audit review. Additional Investigators and/or Study Staff are welcome to attend at the request of the Principal Investigator. An IRB Member may also be present if asked by the IRB.

### Audit Process

The IRB Staff will review all provided materials, included but not limited to, study binders, IRB correspondence, subject consents and authorizations and data collection forms. The IRB Staff will review all supplied paperwork to ensure completeness, organization and adequacy based upon the written protocol, federal guidelines and local IRB expectations. The IRB Staff may compare the study information to that of the IRB files.

### Completion of and Reporting on the Audit

At the completion of the audit the Principal Investigator may request an overview of the findings. Detailed information will be provided in a final report at a later time. IRB staff will complete a detailed report on the audit and its findings to be supplied to the IRB at the next scheduled meeting. The IRB will review the prepared report and make determinations and take actions as necessary based on the audit findings. The final audit report and the IRB determinations will be provided to the Principal Investigator following the IRB meeting. The Principal Investigator may be required to provide a response to the audit findings within a specified time period to be outlined in the review letter with the final report.

### Appeal of the IRB Determinations

The IRB's determination and actions are final and may only be appealed through the CAMC/WVU-Charleston Division IRB's Appeals Policy.