**PURPOSE:** This describes the procedures to when a Sponsor/CRO audit occurs to assess this site’s extent of compliance with regulatory requirements/guidelines and SOP’s for conducting clinical research.

**SCOPE:** This applies to the PI and all relevant staff involved in the audit.

**PERSONNEL RESPONSIBLE:**  Principal Investigator and when delegated by the Principal Investigator---- Sub-Investigators, Study Coordinator and/or other pertinent staff.

**PROCEDURES:**

**Preparing for the Audit**

* Upon notification of an impending audit, immediately contact all members of the research team and the IRB.
* The Study Coordinator or designee will make certain that all required records are available and necessary arrangements are scheduled.
* Ensure that all documentation, including ICF’s, source documents (paper and electronic), CRFs, and the regulatory binder for the study are accurate, complete and available for review by the auditor.
* Ensure that the study drug/device accountability records are accurate, complete and available for review. If there were any instances in which emergency breaking of the blind was required, have that documentation available for review by the auditor.
* Ensure that records of staff qualifications, protocol training and completion of human subject research education are available for review.

**During the Audit**

* The Principal Investigator and designee will meet with the auditor at the start of the audit to discuss the audit process.
* Request to see identification/authorization from the auditor.
* Orient the auditor to their designated work area as well as access to the study documents while on site.
* Accompany auditor during tours and interviews.
* Provide copies of requested study-related documents. *Do not offer information other than what is requested.* The Study Coordinator may keep a copy or record of what has been requested.
* Ensure that questions posed by the auditor are answered by appropriate study personnel.
* The Principal Investigator and designee will meet with the auditor at the conclusion of the audit to discuss any questions or findings.

**Follow-up After the Audit**

* If an audit report or other correspondence is issued, provide a copy of the report to the Principal Investigator, appropriate Manager and the IRB.
* Prepare a response letter and reply to each item in the report, providing clarification or steps that will be taken to institute corrective action.
* Execute corrective action.
* Appropriately submit and file all correspondence related to the audit.