1. **PURPOSE**

To outline the process of a sponsor or Research and Compliance inspection at a clinical research site and describe activities that should be done to facilitate the inspection.

2. **SCOPE**

Applies to Principal Investigator (PI), and when delegated by the PI, additional Investigator(s), Study Coordinators (SCs), and other designated site personnel.

3. **RESPONSIBILITIES**

The PI is responsible for maintaining accurate study documentation, and must be prepared to be audited by the study sponsor or Research and Compliance.

4. **BACKGROUND**

Sponsors and institutions frequently audit investigational sites to inspect for protocol compliance and adherence to the U.S. Code of Federal Regulations, during or after the completion of a study.

Site audits are likely to be conducted if:
- There is high or low enrollment of study subjects
- Problems or concerns with the site have been reported by the monitor or other responsible personnel
- The study is one of extreme importance
- The Investigator’s workload includes several studies with the same sponsor
- The geographic location of the site coincides with other sites being audited

5. **PROCEDURE**

5.1. Upon the request of the sponsor, independent auditor, or Research and Compliance, the PI should have readily available all requested trial-related records.

5.2. Upon notification of an impending external audit, the clinical research personnel who first received notification will inform the PI, Research and Compliance, the SC, and/or the site manager.

5.3. In preparation for the audit, the PI and/or SC will obtain all study-related records, to include Case Report Forms (CRFs), source documents, and Investigator regulatory files.
5.4. The research site will organize all study-related files, arrange logistics, and prepare for the audit according to sponsor or Research and Compliance instructions.

5.5. The PI will designate a liaison to facilitate the audit. This designated liaison will communicate directly with the auditor prior to the audit, if possible, to make certain that all required records are obtained and necessary meetings are scheduled.

5.6. During the audit, the designated liaison will:
   5.6.1. Greet the auditor(s) and verify identification/authorization
   5.6.2. Provide requested records
   5.6.3. Accompany auditor(s) during tours and interviews
   5.6.4. Assist the auditor(s) as needed
   5.6.5. Arrange for follow-up if required

5.7. If possible, the PI will meet with the auditor(s) at the conclusion of the audit to discuss any questions or findings.

6. TERMS & ABBREVIATIONS
   IRB    Institutional Review Board
   PI     Principal Investigator
   SC     Study Coordinator

7. REFERENCES
   7.1. Title 21 CFR 312.62 - Investigator Record Keeping and Record Retention for Clinical Drug or Biological Trials
   7.2. Title 21 CFR 812.140 - Investigator Record Keeping and Record Retention for Device Trials
   7.3. ICH GCP Consolidated Guideline - Part 4.9 Records and Reports
   7.4. ICH GCP Consolidated Guideline - Part 5.15 Record Access

8. ATTACHMENTS
   Human Subjects Audit Checklist for Quality Improvement