***TITLE: SPONSOR, CRO, and/or FDA AUDITS***

***SOP Version #*** RM/CL/FM XX.XX

***Author(s):***

***Approved by Date***

***\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***

***\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***

***Approval:***

***Approved by Date***

***\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***

***\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***

***Revision Version Effective date Description***

***\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***

***\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***

***\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***

**Instructions for modifying this template:**

1. This is a template and should be used as such. Please use this in the manner most appropriate for your research unit.
2. Anything in this template can and may be modified as appropriate for your area while accounting for your interpretation of the most current FDA Guidance.
3. After you have modified this SOP template, do not forget to remove the “Instructions for modifying this template” table.
4. **SCOPE/PURPOSE**

This standard operating procedure (SOP) describes the operations followed at this site when an audit (sponsor/CRO, and FDA), occurs to assess this site’s extent of compliance with regulatory requirements/guidelines and SOPs for conducting clinical research.

This SOP applies to the procedures to prepare for an audit of all clinical studies conducted at this site. It describes the steps followed by the site from the time the audit is scheduled until all follow-up activities associated with the audit have been completed.

**II. ALLOWABLE EXCEPTIONS**

This SOP is meant to be followed without deviation. If a deviation from this SOP occurs, a description of this event will be written and filed with this list of SOPs and the protocol.

1. **RELEVANT REGULATIONS/GCPS**

21 CFR 50: Protection of Human Research Subjects

21 CFR 56: Institutional Review Boards (IRB)

21 CFR 312 Subpart D: Responsibilities of Sponsors and Investigators

GCP: 5.19 Audit

FDA Inspections of Clinical Investigators

**IV. DEFINITIONS/ACRONYMS**

-**Audit**: a systematic and independent examination of trial-related activities and documents to determine whether the evaluated trial-related activities were conducted, and the data were recorded, analyzed, and accurately reported according to the protocol, sponsor’s standard operating procedures (SOP’s), good clinical practice (GCP), and the applicable regulatory requirement(s).

-**CFR**: Code of Federal Regulations

-**Case Report Form (CRF):** a printed, optical, or electronic document designed to record all of the protocol-required information to be reported to the sponsor on each trial subject.

-**CRO**: a person or an organization (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor’s trial-related duties and functions

-**Good Clinical Practice (GCP)**: a standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trials subjects are protected.

-Informed Consent: A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject’s decision to participate. Informed consent is documented by means of written, signed, and dated informed consent form.

-**Principal Investigator (PI):** a person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team.

-**Source Documents**: Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects’ diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories, and at medico-technical departments involved in the clinical trial).

-**Sponsor**: an individual, company, institution, or organization that takes responsibility for the initiation, management, and/or financing of a clinical trial.

-**Standard Operating Procedures (SOP**): detailed, written instructions to achieve uniformity of the performance of a specific function.

-**Sub-Investigator**: any individual member of the clinical trial team designated and supervised by the investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows).

-**Inspector**: representative from the FDA that visits a site to conduct an audit

**V. RESPONSIBLE PERSONNEL**

This applies to those members of the clinical research team involved in arranging, managing, or participating in the audit at this site. Includes the following:

-Principal Investigator (PI)

-Sub-Investigators

-Research Nurse Coordinator

-Data Manager

-Regulatory Compliance Officer

-Research Pharmacist, if applicable

-Support Staff

-Sponsors/CROs

-FDA

**VI. DETAILS**

1. **Preparing for Audit**
2. Notify all parties involved with the study of the upcoming audit. The date, location, and tentative schedule should be included. Ensure that all required personnel are available on the day of the audit.

-Sponsor (if FDA audit), IRB, PI, Sub-Investigators, Research Pharmacy (if applicable), Study staff

1. Reserve work space for the auditor. Ensure that this area is quiet and free of other study records or files.
2. Ensure that all documentation, including informed consent forms, source documents, CRFs, and regulatory binder(s) for the study are accurate, complete, and available for review by the auditor.

-Assemble the requested documentation, as applicable.

-Document and resolve any discrepancies.

-It is helpful to develop a flagging/labeling mechanism so that all pertinent documents are identified and easy for the auditors to find. It is in the research team’s best interest to have everything as organized as possible.

1. Ensure that drug accountability records (if applicable) are accurate, complete, and available for review.
2. Ensure that records of staff qualifications and training are available for review by the auditor.
3. If an FDA audit, you will also need a list of each of the Investigator’s studies for the past two years and their current status.
4. **During the Audit**
5. Meet with the auditor, as scheduled.
6. Verify the credentials of the auditor.

-If it is a FDA audit, request FDA Form 482: Notice of Inspection.

1. Provide the audit package and all documents requested by the auditor, including access to study records and files.
2. Provide copies of study-related documents requested by the auditor (in accordance with institutional privacy policies). Record a list of documents requested by the auditor.
3. Ensure that questions posed by the auditor are answered by appropriate study personnel.
4. Ensure that the required personnel are present at the exit interview: the PI, designated trial staff, and other personnel and/or sponsor representatives, as required.
5. Record the observations given by the auditor, and any discussions.

If this was a FDA audit, request Form FDA 483 if available.

1. **Audit Follow-Up**
2. The auditor or sponsor may communicate inspection observations and/or audit findings to the site. Follow-up with sponsor or auditor to obtain the audit report, if possible.
3. Send a copy of the report to the sponsor, if applicable.
4. Review the audit report with the appropriate staff (including the PI).
5. Prepare written audit response and reply to each item/observation in the report, as soon as possible after its receipt. Include clarification or corrective action that will be taken. Send the response to the sponsor/regulatory agency by the requested date, as applicable.
6. Perform corrective actions as described in the audit response.
7. File audit documents in appropriate study files at the site.

**VII. QA**

NA

**VIII. APPENDICES/RESOURCES**

NA

**IX. RELATED SOPS**

NA