# [SITE NAME]

## STANDARD OPERATING PROCEDURE

| Title: | | No.: ISCORE-RC-102.00 | |
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| **External Audit Management** | | Page 1 of 5 | |
| | | Date of Issuance: dd, month, yyyy | Date Effective: dd, month, yyyy |
| | | Supersedes: NA | |
| Prepared by: | Reviewed by: | Approved by: | |

**Purpose:**

This standard operating procedure (SOP) describes the operations followed at [SITE] campuses when a routine/not-for-cause or for-cause external audit (sponsor/CRO, Food and Drug Administration (FDA) or other regulatory agencies) occurs to assess the site's extent of compliance with regulatory requirements designed to insure the safe and effective conduct of clinical research.

**Scope:**

This SOP describes procedural pathways to prepare for an audit of all clinical studies conducted at the site. It describes the steps followed by the site from the time that the audit is scheduled through all follow-up activities associated with the audit responses to the findings. This SOP excludes external audits directed at Institutional Review Board (IRB) compliance reviews.

**Definitions:**

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 (SOPs), good clinical practice (GCP), and the applicable regulatory requirement(s). [ICH E6]

Inspection: The act by a regulatory authority(ies) of conducting an official review of documents, facilities, records, and any other resources that are deemed by the authority(ies) to be related to

the clinical trial and that may be located at the site of the trial, at the sponsor's and/or contract research organization's (CROs) facilities, or at other establishments deemed appropriate by the regulatory authority(ies). [ICH E6]

Form 482: FDA Notice of Inspection Form.

Form 483: FDA Notification of objectionable conditions.

Inspector/Auditor: The representative of the Regulatory Agency (Inspector) or Sponsor (Auditor) performing the audit.

**Materials:**
Audit Checklist
Employee Guidelines during the Audit Process

**Responsibility:**

This SOP applies to the clinical departments and [SITE] institutions actively engaged in clinical research involving human subjects.

**Procedure:**

A. Preparing for the External Audit

Note: For unannounced regulatory agency audits, the inspectors should be placed in a private area such as a conference room upon arrival and the [appropriate site-specific office] contacted immediately. The steps below will then be followed as applicable.

1. Notification of appropriate parties will be performed in a timely manner according to the type of external audit:
    a. Regulatory Agency Audit:

When notified of a Regulatory Agency audit, such as the FDA, immediately contact the [appropriate site-specific office]. A(n) [appropriate site-specific office] representative will assist to establish the name(s) and credentials of the inspector(s), the scope of the inspection (routine or for-cause) and agree on all dates/availability in advance. The representative will help coordinate the visit and will distribute the information as soon as possible to:

i. The Sponsor
ii. The [SITE] Institutional Review Board (IRB)
iii. The IRB of record, if not the site's IRB
iv. The Office of Sponsored Programs (OSP) Office
v. [Site-specific] Internal Audit Team, Legal Counsel

vi. the Chair of the department/institution, Principal Investigator (PI) and Research team, including Laboratory, Pharmacy and any other personnel/departments involved with the conduct of the trial(s) identified.

b. Sponsor/Cooperative Group Audit

If notified of a Sponsor/Cooperative group audit, a designated clinical trials team representative will coordinate the visit and will inform:

i. [Site-specific oversight group] who will provide assistance as needed and oversight of the audit process

ii. [Site-specific oversight group] Internal Audit Team

iii. The Institutional Review Board (IRB)

iv. The IRB of record, if not under local oversight

v. The Office of Sponsored Programs (OSP) Office

vi. The PI and Research team, including Laboratory, Pharmacy and any other personnel/departments involved with the conduct of the trials.

2. Ensure that all documentation, including informed consent forms, source documents, Case Report Forms (CRF)s, and the regulatory binder for the trial identified as the focus of the audit are accurate, complete and available for review by the auditor. The Audit Checklist should be used as a guide.

3. 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, the documentation should be available.

4. Ensure that records of staff qualifications and training are available for review by the auditor.

5. As time allows, prepare staff for the audit using the Employee Guidelines during the Audit Process.

6. For a Regulatory Agency audit, reserve at least 2 conference rooms, as possible, one for the inspector and one for material preparation for the estimated duration of audit.

B. During the audit:

1. An audit lead/host will be designated by [SITE] Research Leadership and will meet with the auditor/inspector and request to see identification to confirm name and credentials.
2. If this is an FDA audit, request Form FDA 482 (Notification of Inspection). For Regulatory Agency audits, a [Site-specific oversight group] representative will participate in tours, interviews and preparation of documents for audit.
3. Provide an SOP index, organizational charts, and other documents as deemed appropriate, orientation and access to the study records and tour of requested departments/areas, as applicable to the auditor/inspector.
4. Provide copies of requested study-related documents. A Quality Control review will be performed by a quality assurance representative and/or members of the research team for all documentation to ensure it is complete prior to being provided to the auditor/inspector as possible.
5. For a regulatory agency audit, copies will be made of every document provided and kept as part of the audit documents and conversations will be documented by a scribe, as possible.
6. Regulatory agency inspectors will not be given access to the Electronic Medical Records [SITE EMR], however printouts will be provided. If direct access is specifically requested, then [Site-specific oversight group] personnel will navigate the system for the inspector.
7. Ensure that questions posed by the auditor/inspector are answered by appropriate study personnel.
8. Written daily summaries will be provided by the host of the audit to key personnel/management and will include:
   - Documents/tours provided
   - Any issues found
   - Tasks to be completed prior to next scheduled audit date

C. Post-Audit Follow Up

1. The Principal Investigator, audit lead and [SITE] Research Leadership will participate in the exit meeting with the auditor/inspector. A representative from [Site-specific oversight group] Internal audit and [SITE] IRB should also attend for Regulatory Agency audits.

   If this was an FDA audit, request Form FDA 483, if issued. Form 483 will be distributed to the Sponsor, the IRB, the PI and the OSP, and [SITE] Research leadership redacted as needed.

2. A lead person for the response will be designated by [SITE] Research Leadership and will direct efforts to generate the response to the audit report/Form 483 as soon as possible after its receipt, within the expected deadline. Reply to each item in the report, providing clarification or steps that will be taken to institute corrective and preventive actions based on the identified root cause(s) of the issues.

In the case of a Regulatory Agency audit, generally the lead person for the response will be an [site-specific oversight] representative. The clinical research team will provide clear and objective responses on each regulatory audit finding to the [site-specific oversight] representative to include in the response. For an FDA Form 483, a response must be provided within 15 working days.

Sufficient time should be planned for review of the response by designated reviewers from [SITE] Research Leadership.

3. Send the final response to internal personnel and departments as needed.
   For Regulatory Agency audits, the response will be distributed to the Sponsor, the IRB, the PI, [Site-specific oversight group] Internal Audit office and the OSP. A [Site-specific oversight group] representative will send the initial response to the Regulatory Agency and any subsequent response until all findings are closed.

   In the case a warning letter is issued by the FDA, notification will be provided to the groups identified in section A.1.a. Steps C.2 and C.3 above will be repeated.

   For Sponsor/Cooperative group audits, the response will be prepared by the clinical research team and provided to the Center of Excellence once finalized. A [Site-specific oversight group] representative can assist with the response as needed.

4. The [Site-specific oversight group] will perform periodic verifications that all audit findings and corrective/preventive actions have been closed out in a timely manner.

## History of Revisions to SOP

| Effective Date | Nature of Revision |
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