[SITE NAME]

STANDARD OPERATING PROCEDURE

Title:		No.: ISCORE-RC-121.00	
External Monitoring/Access		Page 1 of 4	
		Date of Issuance: dd, month, yyyy	Date Effective: dd, month, yyyy
		Supersedes:	
Prepared by:	Reviewed by:	Approved by:	

Purpose:

This standard operating procedure (SOP) describes the operational guidelines followed by the [Site Location], [Site Name], [Site Institution] and affiliated health systems regarding external monitoring.

Scope:

This SOP describes procedural guidelines for on-site and centralized (remote) monitoring during a clinical trial to ensure protection of the rights, welfare, and safety of human subjects, quality of the clinical trial data and compliance with the protocol, Good Clinical Practice (GCP) and applicable regulatory requirements.

Materials:

N/A

Responsibility:

This SOP applies to the [Site Name] Institutions and associated clinical departments actively engaged in clinical research involving human subjects.

Definition:

Monitoring: The act of overseeing the progress of a clinical trial, and ensuring that it is conducted, recorded, and reported in accordance with the protocol, standard operating procedures (SOPs), Good Clinical Practices (GCP), and the applicable regulatory requirements.

- On-Site Monitoring: In person evaluation carried out by sponsor personnel or representatives at the site.

- Centralized (remote) monitoring: Is a remote evaluation carried out by sponsor personnel or representatives at a location other than the sites at which the clinical investigation is being conducted.

Procedure

The process for monitoring shall be communicated to all external sponsors during the site qualification and/or initiation visit. And the CRO/Sponsor must notify the staff in writing, prior to study activation, if the monitoring process is not acceptable so that objections can be reconciled accordingly.

The PI and delegated research team members will permit monitoring and auditing by the sponsor and inspection by the appropriate regulatory authorities.

1. Scheduling a Monitoring Visit (on-site or centralized/remote)

    a. The PI, appropriate research team member (e.g. coordinator) and monitor shall arrange a mutually agreed upon date and time to conduct the monitoring visit, that allows sufficient time for requirements to be coordinated (e.g. monitoring space, staff availability and system access).
    b. Visits must be scheduled during regular business hours and may vary in frequency according to the protocol.
    c. A research team member (e.g coordinator) should submit requests for the monitors to access relevant electronic records or documents to the appropriate departments at least two weeks in advance such as for the electronic medical records [Site's EMR system], regulatory files, drug accountability files and/or case report forms. Specific forms (refer to system SOPs) may also be required for direct access to study related electronic files (e.g. eReg).
    d. The sponsor shall provide a confirmation letter of the scheduled visit and confirm the following:
        i. Date(s) of the visit
        ii. Protocol(s) to be reviewed
        iii. Documents planned for review (e.g. patients, visits, regulatory) and any locations requested to be viewed/toured (e.g. pharmacy, clinics)
        iv. Individuals required to participate in the visit (e.g. Principal Investigator, Investigational Pharmacist)
        v. Number of monitors
        vi. Facilities required (e.g. computer, internet access, Electronic Medical Record ([Site's EMR system]) access)
    e. Any visit (on-site or remote) that must be rescheduled shall be done so at the research team's discretion.

2. Preparing for the Monitoring Visit (on-site or centralized/remote)

a. Alert the pertinent research staff with the scheduled monitoring date(s), including the investigational pharmacy, if applicable.

b. During an on-site or remote monitoring visit, direct access to the relevant study related documents shall be required. Documents may include, but are not limited to:
   - Regulatory documents
   - Screening documents
   - Informed consent forms
   - Patient medical records
   - Laboratory/Diagnostic test results
   - Drug Accountability records
   - Specimen handling records
   - Case Report Forms (CRFs)

c. Ensure that all documentation and case report forms are complete and available for review.
d. Ensure that all data queries and/or previous monitoring findings received to date have been resolved to the extent possible.

3. During the On-Site Monitoring Visit

a. Upon arrival, ensure that the monitor completes the Monitoring Visit Log and direct the monitor to the designated area.
b. Delegated research team members shall be available to assist throughout the day. The PI will be available as needed.
c. Provide tours of clinic and other facilities as requested.
d. Provide the monitor with the study related documentation, patient data and access as agreed upon in the confirmation visit letter. Monitors should only have access to the information that was requested. Monitors should be instructed to immediately alert the staff if access was inadvertently granted to information not relevant to the study.
e. Provide the necessary equipment for access to the [Site's EMR system] (e.g. computer or network access) and assist as needed.
f. Discuss the best method for communication regarding queries and/or photocopying requests during the visit. Photocopying should be performed by the designated study personnel.
g. Monitors are not permitted to print, or photocopy protected health information (PHI). Monitors should be informed that removing PHI in any format from this site is prohibited.

4. During the Remote Monitoring Visit

a. Verify and apply points from section 3 as relevant.
b. Request documentation of monitoring visit (e.g. Signed/scanned visit log or other).
c. The monitor will provide information for any virtual meetings needed (e.g. WebEx, Zoom or other)
d. If verification of facilities is needed, an agreement on a suitable alternative to an in-person tour should be available.
e. If needed, documentation can be scanned into an appropriate secure platform to which monitors can be provided access (deidentified as applicable).
f. Electronic files will be accessible for a period of time as agreed for the monitoring visit.

5. Conclusion of the Visit

a. At the conclusion of the visit, the monitor(s) may request a meeting with the research team to discuss study related issues which may include but not limited to:
   - Adherence to the protocol (deviations)
   - SOPs
   - Review of the regulatory files
   - Verification of data in the CRFs with the source documentation
   - Investigational product storage, dispensing and accountability requirements for data storage

b. Within two (2) weeks of the last day of a visit, a written monitoring report should be received from the sponsor representative. This report shall include the study number, study title, and a summary of what the monitor reviewed and the significant findings, deviations, conclusions, actions taken or to be taken to secure compliance.

c. The PI and research team members shall address all findings presented by the monitor within two weeks as possible, and any corrective action(s) shall be documented and filed accordingly.

d. If a written monitoring report is not received within two weeks of the visit, a study team member shall contact the sponsor representative. If no report is provided following the communication, a study team member shall provide written communication to the sponsor to advise future visits for the study will not be scheduled and any already scheduled may be cancelled if follow up has not been received.

e. Monitoring reports and evidence of resolution should be filed in the applicable trial master file (TMF).

References

E6 (R2) Good Clinical Practice: Integrated Addendum to ICH E6 (R1) Guidance for Industry
FDA Guidance for Industry, Oversight of Clinical Investigations – A Risk Based Approach to Monitoring

History of Revisions to SOP

Effective Date	Nature of Revision
dd, month, yyyy	New SOP