Clinical Research Enterprise (CRE)

Standard Operating Procedures

Monitor Visits (On Site or Remote)

SOP #: 3.04

Version: 7.0

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Approval:

Approved By		Date
	Electronically signed by: Thomas Patrick Frazier Reason: I am the approver. Date: Apr 26, 2025 14:29 CDT	04/26/2025
	Electronically signed by: Felice Cook Reason: signature needed on regulatory documents Date: Apr 26, 2025 15:04 CDT	04/26/2025

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7.0	04/26/2025	

Purpose

The purpose of this Standard Operating Procedure (SOP) is to outline the required processes for monitoring clinical research studies to ensure compliance with sponsor, Contract Research Organization (CRO), and Clinical Research Enterprise (CRE) requirements. This SOP is designed to support the accuracy, integrity, and timely resolution of data queries and any other findings identified during monitoring visits. It is intended to align with applicable U.S. Food and Drug Administration (FDA) regulations and Good Clinical Practice (GCP) guidelines.

Scope

This SOP applies to the following: all CRE staff, Sponsors/CROs.

Allowable Exceptions

On a case to case basis with prior approval from CRE Executive Leadership.

I. Scheduling

a. **Monitor Informational Packet**
New monitors must be provided with the Monitor Informational Packet prior to any remote or onsite monitoring visit. This packet is designed to assist the monitor in preparing for and conducting their visit. The Study Coordinator is responsible for sending the packet once the primary monitor for the study has been identified.

b. **Monitoring Visit Timing and Coordination**
Monitoring visits must be scheduled in advance and conducted on regular business days between 8:30 AM and 4:00 PM CST. The Study Coordinator and the monitor share responsibility for coordinating these visits. If the monitor requests meetings with the Principal Investigator (PI), pharmacy, or other

departments, the Study Coordinator must coordinate and confirm those appointments prior to the visit.

c. Scheduling Process and EMR Access
Monitoring visits are scheduled using the **Fillable Monitor Request Form**. Once submitted, the Regulatory Coordinator (Ronald Prevatt) will send a calendar invitation to all regulatory personnel and the Study Coordinator, with key details included in the subject line. If EMR access is required, Ronald will initiate the access request process. The Study Coordinator will be cc'd on all related correspondence to ensure timely follow-up on all tasks and monitor-related needs. **Form Link:** Fillable Monitor Request Form
Monitoring visits should be requested a **minimum of four (4) weeks in advance** for **new monitors** and **at least three (3) weeks in advance** for **established monitors**.

d. **Work Space and Access**
If applicable, a designated work location will be provided for the monitor with access to appropriate research staff. The Study Coordinator is responsible for securing this space, reserving it, and notifying the regulatory team of the location.

e. **IMV Letter Requirement**
It is expected that monitors will submit the IMV (Interim Monitoring Visit) letter to the Study Coordinator **no later than two (2) weeks prior** to the scheduled visit, to ensure sufficient preparation time.

f. **EMR Access Verification**
Monitors must submit a screenshot showing successful access to **CERNER/IMPACT** at least **one (1) week prior** to the visit. It is the monitor's responsibility to install all the required software and confirm access independently. Failure to do so will result in the visit being canceled and rescheduled.

g. **Follow-up for EMR Access**
If the Study Coordinator has not received the required screenshot one week prior to the visit, they must contact the monitor to confirm access setup (e.g., username, password, token, etc.). If the monitor does not respond within **two (2) business days**, the visit will be canceled and rescheduled.
Please note: **Over-the-shoulder EMR viewing is not permitted**. In addition, **printing or certifying source documents available in the EMR will not be accommodated.**

II. Day(s) of Monitor Visit

a. Study Coordinator Support
During the monitoring visit, the Study Coordinator will ensure that all relevant study documentation is available for review. The Study Coordinator will be present in the morning to welcome the monitor, assist with room setup, and provide general guidance on navigating the EMR system if required. Note that

this support does not include technical troubleshooting or extended IT assistance. Monitors are encouraged to refer to their training materials for EMR navigation as needed.

b. **Communication During Visit**
The Study Coordinator will establish the preferred method of communication for the duration of the visit and coordinate how queries and follow-ups will be addressed throughout the day.

c. **Exit Interview and Oversight**
If requested, the Research Nurse Manager will review monitoring findings. The Study Coordinator will ensure that an adequate time is reserved at the end of the visit for an exit interview with the monitor if needed. The exit interview will be conducted after all CRFs, and regulatory documents have been reviewed by the monitor.

d. **Building Access**
Monitors are restricted to their assigned monitoring room and the restrooms. Access to any other areas of the research facility requires accompaniment by a staff member.

e. **Additional Access Charges**
A monitoring visit fee will be assessed to the sponsor/CRO for any non-routine visit that includes access to the e-regulatory binder outside of standard monitoring visit scope.

III. Regulatory documents

a. **Issue Resolution**
The Clinical Research Regulatory Coordinator is responsible for addressing any regulatory deficiencies identified during the monitoring visit.

b. **Preparation and Access**
The Regulatory Coordinator will prepare the regulatory binders and place them in the monitor room either the day before or the morning of the visit. For studies utilizing the Florence e-regulatory system, the Regulatory Coordinator will confirm the monitor's access to the platform prior to the visit. The Regulatory Coordinator will also meet with the monitor during the visit to review any concerns and work to resolve them before the monitor departs.
Monitors are not permitted to remove any original regulatory or study-related documents from the research offices.

IV. Participant documents

a. **Issue Management**
The Study Coordinator is responsible for resolving monitoring findings related to the clinical conduct of the study. Any major deviations or significant findings must be promptly communicated to and reviewed with the Research Nurse Manager.

b. **Document Preparation**
The Study Coordinator must ensure that participant source documents and CRFs are complete, current, and accessible. Prior to the visit, the Study Coordinator will organize and place all requested participant documents in the monitor room for review.

V. Conclusion

a. **Post-Visit Summary**
Upon completion of the visit and the exit interview, the monitor is expected to provide a written summary of all findings—both clinical and regulatory—within two (2) weeks. This summary must be sent to the Study Coordinator, Regulatory Coordinator, and Principal Investigator.

b. **Document Return**
Following the visit, the Regulatory Coordinator will return all regulatory documents to their appropriate location, and the Study Coordinator will do the same for participant and study documentation.

c. **Room Clean-Up**
The Study Coordinator and Regulatory Coordinator are responsible for ensuring that the monitoring room is cleaned and restored to its original condition after use.

d. **Distribution of Follow-Up Communication**
Once the monitoring follow-up letter is received, the Study Coordinator will forward it to their Lead Coordinator and copy the Regulatory Coordinator, Regulatory Manager, and Nurse Manager.

e. **PI Review and Documentation**
The monitor’s follow-up letter must be reviewed and signed by the Principal Investigator (PI), either in person or electronically (e.g., Adobe Sign), depending on the sponsor's requirements. The Regulatory Coordinator will file the signed letter and submit any necessary corrective actions to the IRB as applicable.

VI. Screenshot Example