Procedure Name: Sponsor Monitoring Visits	**Number:** SOP 10 v3.0
Subject: Clinical Research	**Effective Date:** July 01, 2004
Linked Policy: Clinical Research Operations & Compliance Policy	**Revised Date:** March 01, 2023

PURPOSE:

To establish the GW Medical Faculty Associates ("MFA") procedure for scheduling an industry sponsored research monitoring visit and what is expected during a monitoring visit.

SCOPE:

This standard operating procedure ("SOP") applies to all research team members responsible for scheduling and participating in research monitoring visits.

RESPONSIBILITY:

This SOP sets forth responsibilities for research team members involved with scheduling and participating in research monitoring visits that involve clinical research studies conducted at the MFA. The Principal Investigator ("PI") retains this responsibility unless the PI has expressly delegated this duty to another research team member and the delegation is documented on a study specific Delegation of Authority Log.

PROCEDURES:

Scheduling the Monitoring Visit

Work with the study monitor to schedule a mutually convenient date and time with necessary staff members (ie. PI and Pharmacy) to conduct the monitoring visit and notify necessary staff members of the scheduled visit date and time. If using an electronic regulatory system, make sure to grant the monitor access to the electronic binder for the date and time. **NOTE:** Monitoring visits should be confirmed in writing in the form of a Site Visit Confirmation Letter sent directly from the monitor or CRA.

Case Report Form/Source Records Preparation

1. Assure that CRFs for all subjects are current and complete;
2. Assure that all requested source documents, including consent forms and other medical charts or information are available for the monitor to review
3. If there is a study drug, include temperature records for where the drug is stored; and
4. Assure that all queries received to date have been resolved to the extent possible.

Regulatory File Notebook

1. Review regulatory files for completeness and accuracy.

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2. Identify any missing documents and request copies of the documents from appropriate people, e.g., IRB for documentation of submission of an IND report, sponsor for copy of a protocol amendment.
3. File the Site Visit Confirmation Letter.
4. Make sure all staff on the DOA log has been signed off by the PI, IRB approved, and all have the appropriate trainings completed BEFORE starting any study activity.
5. If the monitoring visit is being conducted remotely, grant the monitor access to the electronic binder for the specified date and time.

Managing the Monitoring Visit

1. Develop a monitoring visit log, if not provided by the CRO/Sponsor and assure that the monitor signs the log designating the purpose of the visit and that a GWU MFA research team member countersigns for each visit; See Sample Monitoring Log.
2. At the conclusion of the visit, PI and coordinator should meet or speak with the monitor over the phone as soon as possible to discuss any issues identified.

EPIC Access for the Monitoring Visit

1. Please reference the EPIC Access Monitoring Guidance document on the process for submitting and granting monitor access into EPIC.
2. Assure that the form is submitted at least one week before the scheduled monitoring visit.

Follow-up after the Monitoring Visit

1. Assure that all issues identified for resolution or follow-up are addressed;
2. Ascertain if a written report of the visit will follow in addition to any documentation that is left at the site by the monitor;
3. Assure that any issues identified in the written report are addressed with documentation retained in the regulatory binder; and
4. Maintain a copy of all monitoring visit letters and reports.

Review and Revision

This SOP shall be reviewed every 2 years. This SOP may be reviewed more frequently if it does not reflect current operations.

Attachments

Sample Monitoring Visit Log

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REFERENCES:

21 CFR 312.62	Investigator recordkeeping and record retention.
21 CFR 812.140	Records.
ICH E6 (R2)	Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice E6 (R2)
	Section 8.3.25
MFA Clinical Research SOPs	EPIC Monitoring Access Guidance Document

Office of Clinical Research

MONITORING VISIT LOG

Protocol ID: _____ IRB #: _____ PI: _____ Sponsor: _____

Date of Visit (dd/mm/yy)	Printed Name and Signature		Visit Purpose*
	Investigator or Representative (Printed name and signature)	Site Monitor, Sponsor or Representative (Printed name and signature)	

***IV = Initiation Visit; IM = Interim Visit; AU = Audit; CO = Close Out; O = Other (specify)**