# BCM Office of Clinical Research: OCR-P-03-01

## Coordinating Monitoring Visits

**Introduction**

This procedure describes the process for preparing and coordinating clinical research monitoring visits. This procedure applies to all clinical research studies conducted by a Baylor College of Medicine Investigator, within BCM or affiliate facilities.

**Prior to monitoring visit**

The Principal Investigator (PI) or designee is responsible for coordinating monitoring visits when a study monitor notifies the site of an upcoming visit:

| Step | Actions by Study Staff |
|---|---|
| Notification | Confirms the availability of study personnel and service areas. |
| Scheduling | • Schedules monitoring visit at a mutually agreeable time after confirming availability of Principal Investigator (PI), Regulatory Coordinator (Reg C), Investigational Drug Services (IDS) and other study team members, as applicable.<br>***Note*:** Access to the Study Site and/or Study Documents will be allowed only for the duration of the scheduled monitoring visit, during normal business hours unless otherwise approved by the study PI and/or study staff supervisor.<br>• Makes a reservation of workspace for monitor, such as conference room or cubicle as applicable.<br>• Confirms that all BCM affiliate requirements for monitor access are met, as required for the conduct of the scheduled monitoring visit.<br>• Provides schedule confirmation to study monitor. |
| Preparation | • Ensures that regulatory documents, case report forms (CRFs), and subject binders are organized and reviews documents for completeness and accuracy.<br>• Confirms that any outstanding items from previous monitoring visits are addressed. |
| Drug and Device Accountability Records | • Investigational Drug Services, or study staff if applicable, review drug supplies and drug accountability records for completeness and accuracy, if applicable.<br>• For device studies, study staff reviews device supplies, storage and device accountability records for completeness and accuracy. |
| Set-Up of Monitor Access | • Designated study staff confirms monitor access to all physical and electronic records required for their job duties as applicable.<br>• Study staff or designee requests individual access to electronic medical record (EMR) for the monitor, if applicable. Individual access is required when monitor reviews source documents in the EMR without direct support from study staff. |

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# Coordinating Monitoring Visits, Continued

**Monitoring visit**

During the monitoring visit, study staff take the following actions:

| Step | Actions by Study Staff |
|---|---|
| Binders in place | Ensures that subject binders and regulatory binders, are available in the monitoring area prior to monitor's arrival. |
| Monitor greeting and orientation | • Greets and escorts the monitor to designated monitoring area.<br>• Discusses visit schedule and provides orientation as needed.<br>– Assists the study monitor with passwords to access EMR, fax, copier, Wi-Fi, etc. as applicable.<br>– Ensures that the monitor signs monitoring visit Log.<br>– If restricted access has not been set up, study staff stays with the study monitor to assist with access and navigation of electronic medical records and to assure patient confidentiality. |
| Staff available for queries | Responds to monitor queries during monitoring visit. |
| Monitor request for documents | Replaces patient identifiers with study identifiers on copies of documents provided to the monitor. |
| Remote monitoring | For remote monitoring visits, grants access to all applicable electronic records for the duration of the scheduled monitoring visit. |
| PI and staff meeting with study monitor | PI and/or study staff meet with study monitor to discuss issues or outstanding queries, if applicable. |

**Follow-up to monitoring visit**

The PI reviews a copy of monitoring report and queries, and forwards to applicable study staff for review, filing in regulatory binder, and addressing findings.

**VERSION/REVISION HISTORY:**

| Approval Date | Version | Owner | Approver | Revision Summary |
|---|---|---|---|---|
| 10-13-21 | 01 | OCR | Catherine Simmons (CS), Jose Rodriguez (JR) | |