BCM Office of Clinical Research: OCR-P-32-01

Physical Access to Study Sites and Study Documents

Introduction

This procedure applies to Study Monitors/Sponsor Auditors (SM/SA) that require access to BCM Study Sites and/or Study Documents for the purpose of study monitoring or site qualification determination.

A Study Site is defined as the location where study documents are housed or where study activities may occur.

Requests for access

After receiving the request for access to the Study Site and/or Study Documents, the Principal Investigator (PI) or designee schedules the Study Visit (SV) with the SM/SA. Study team members should be notified of the SV, as applicable.

Study site and document requirements

The following are study site and document requirements to be observed during site visit by study team members:

- Physical access to the Study Site and/or Study Documents will only be allowed during normal business hours unless otherwise approved by the study PI.
- The SM/SA shall only be granted access to the facilities, services, data which are required to perform their job duties.
- The designated space shall not be located in patient areas or areas where patient PHI may be overheard or seen. The SM/SA shall be escorted by study staff in all patient or secure areas.
- Documentation of the SV (e.g. study visit log) shall be maintained with the study documents.
- The SM/SA will not remove documents from the study site to conduct source data verification and the SM/SA will not photocopy documents with subject PHI. If it is necessary for the SM/SA to photocopy documents, they must be de-identified before removal from the study site and only with the approval of the study Principal Investigator (PI).
- Study staff must comply with the BCM policy for BCM Information Assets (Policy 12.1.15).
- Violations shall be reported to the BCM Integrity Hotline

Study monitor/ Sponsor auditor arrival

Study staff meeting the SM or SA proceed as follows:

- Confirms identity and escorts SM/SA to Security to obtain a visitors badge, as applicable. For site visits that occur at a BCM Affiliate, the Affiliate visitor policy will be followed.
- Escorts the SM/SA to the designated area where study documents have been placed for SM/SA review.

Physical Access to Study Sites and Study Documents, Continued

Related standards   BCM Information Assets, [Policy 12.1.15](#)

VERSION/REVISION HISTORY:

Approval Date	Version	Owner	Approver	Revision Summary
5/26/21	1	OCR	Catherine Simmons (CS), Jose Rodriguez (JR)	