### 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.

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Related standards

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<thead>
<tr>
<th>Related standards</th>
<th>BCM Information Assets, Policy 12.1.15</th>
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**VERSION/REVISION HISTORY:**

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<td>Catherine Simmons (CS), Jose Rodriguez (JR)</td>
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