Sponsor Monitor Visit

VCU/VCU Health CLINICAL RESEARCH STANDARD OPERATING PROCEDURES

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1. PURPOSE

This Standard Operating Procedure provides basic procedures and guidance to be used when an external monitor, such as a sponsor or sponsor-representative (e.g., appointed Clinical Research Organization) visits (remote or on-site) VCU/VCU Health to conduct monitoring or auditing visits regarding the organization's ongoing clinical studies conducted at VCU/VCU Health facilities, affiliates, and participating sites.

This policy applies to all ROUTINE monitoring visits (sometimes referred to as scheduled or routine monitoring visits) conducted by external sponsors. *This policy does not apply to audits or inspections by the Food and Drug Administration or the National Institutes of Health or other non-routine visits.*

2. GUIDELINES

At a monitoring visit the sponsor, clinical research organization, or other monitor will outline specific monitoring requirements which may also be outlined by a sponsor contract or other document. Typically the study processes for the site are reviewed, which include:

- Assessing adherence to the protocol;
- Reviewing regulatory files for completeness;
- Ensuring appropriate test article storage, dispensing, and accountability, if applicable;
- Verifying the validity, accuracy and quality of the data in case report forms (CRFs) or data collection forms against original source documentation; and,
- Meeting with the research coordinator and principal investigator to discuss progress of the study and findings or concerns as a result of this or previous monitoring visits.

3. DEFINITIONS

Monitoring- The act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, standard operating procedures, good clinical practice, and the applicable regulatory requirement(s).

On-Site Monitoring- An in-person evaluation carried out by sponsor personnel or representatives at the sites at which the study is being conducted. On-site monitoring can identify data entry errors (ex: discrepancies between source records and case report forms

(CRFs)) and missing data in source records or CRFs; provide assurance that study documentation exists; assess the familiarity of the site's study staff with the protocol and required procedures; and assess compliance with the protocol and investigational product accountability (when applicable). On-site monitoring can also provide a sense of the quality of the overall conduct of the trial at a site (ex: attention to detail, thoroughness of study documentation, appropriate delegation of study tasks, appropriate clinical investigator supervision of site staff performing critical study functions). On-site monitoring can therefore be particularly helpful early in a study, especially if the protocol is complex and includes novel procedures with which the clinical investigator(s) may be unfamiliar. Findings at the site may lead to training efforts at the site.

Centralized Monitoring- Remote evaluations carried out by sponsor personnel or representatives at a location other than the sites at which the clinical investigation is being conducted. Centralized monitoring processes can provide the same capabilities of on-site monitoring.

4. PROCESS

Monitoring visits will normally be arranged in advance by the monitor with the Principal Investigator and/or other staff at regular intervals, soon after the first trial participant t is enrolled. The frequency of monitoring visits will depend on a variety of factors, including the study nature, recruitment rate, and performance of the study site staff.

A. Prior to scheduling a monitoring visit:

- Verify monitor has access to the electronic health record (EHR). Access (EpicCare) should be obtained prior to the visit. The process should occur well in advance, ideally during the study start-up phase. Sponsor monitors must follow VCU Health SOP Clinical Research Sponsor/Contract Research Organization Representative Electronic Health Record & Facility Access to gain access to the EHR. If the monitor does not complete the requirements for access to the EHR prior to the visit access will not be granted.
- The PI or their designee is responsible for informing key research personnel and applicable department(s) of the date and time of a monitor visit including, but not limited to, investigational pharmacist(s) and other clinical care/ancillary personnel or departments.
- If coming on site, the PI or their designee should ensure that appropriate space is available to successfully conduct the visit. The space should afford privacy, access to necessary office equipment and be removed from patient care areas and unrelated study files. Monitors should conduct the review in the assigned space. Monitors planning to come on site are permitted in university spaces. However, those needing to come to a VCU Health space requires registration through the VCU Health credentialing system and must request an appointment. Reference VCU Health SOP

Clinical Research Sponsor/Contract Research Organization Representative Electronic Health Record & Facility Access for additional information.

- Upon scheduling a monitoring visit, the monitor should provide the study team a confirmation letter confirming the scheduled visit and provide a list of items to be reviewed within a reasonable time frame prior to the visit.
- The PI or their designee should prepare the following documents so that the sponsor monitor has all the documents required to complete the monitoring visit including:
    - Regulatory documents - confirm all regulatory documentation is complete and available for review by the sponsor monitor.
    - Research participant research records - confirm all case report forms are complete and available for review by the sponsor monitor.
    - Investigational accountability records (if applicable)
    - Source documents, such as medical records, radiology reports, laboratory reports, informed consent forms, are available for source data verification by the monitor
    - Information on any protocol violations and safety issues such as unexpected adverse events and any serious adverse events that happened at the site (if applicable).
- For studies utilizing Veeva SiteVault to maintain the study's documentation, the monitor must have a Veeva ID prior to the visit. Procedures on setting up a monitor account should be followed as outlined in "Monitoring and Source Documentation for Clinical Studies Utilizing Veeva SiteVault."
- Ensure the quantity of investigational products (IP) is checked and the relevant logs are updated (if applicable).
- For studies utilizing Vestigo, reference VCU Health's Investigational Drug Services instructions for remote monitoring.
- Ensure the quantity of biological samples is checked and the relevant logs are updated (if applicable).
- Should a monitor need to visit another department or area of the facility, arrangements should be made with the applicable department.
- Confirm all outstanding issues from previous visits and data queries have been resolved

B. During a monitoring visit:

- The PI, clinical research coordinator (CRC), and any other relevant members such as the co-investigator and/or the pharmacist should be available on the day(s) of the visit, in order to clarify any details and answer any queries raised by the monitor.
- Ensure access to the following documents:
    - Regulatory documents
    - Research participant research records
    - Investigational accountability records (if applicable)

    - Source documents, such as medical records, radiology reports, laboratory reports, informed consent forms,
- The sponsor monitor will review all aspects of the study, including, but not limited to:
    - Adherence to the protocol
    - Review of the regulatory files
    - Verification of the data in the (e)CRFs with the source documentation
    - Investigational product storage
    - Dispensing and accountability requirements
- Should a monitor need to visit a patient area, an area with patient information, or biological samples, they must be accompanied by key study personnel at all times.
- The CRC should facilitate the monitor's check on the IPs and biological samples.
- The monitor will usually request to meet with the PI towards the end of the visit to review any issues. The CRC and relevant members should discuss any findings or outstanding issues raised by the monitor following his or her review.
- If the monitor indicates inconsistencies found in the data on the CRF, the CRC may correct the data during the visit.

C. After a monitoring visit:
- The PI will receive a follow-up letter/communication from the sponsor detailing the results of the monitoring visit. The follow-up letter/communication must be filed in the regulatory binder.
- The investigator and CRC should follow up and resolve any issues raised by the monitor. It is the responsibility of the PI, with the support of the appropriate VCU/VCU Health staff, to ensure that all outstanding items are satisfactorily addressed in a timely manner.

5. REFERENCES

A. Code of Federal Regulations
- Drug/Biologics: 21 CFR 312.56 – Review of ongoing investigations
- Devices: 21 CFR 812.46 – Monitoring Investigation

B. Good Clinical Practice
- ICH Harmonised Guideline Guideline For Good Clinical Practice E6(R3)

C. VCU/VCU Health
- VCU Compliance Notice 17-002 Notification Requirement for Research Subject to External Audit or Inspection (reference only for non-routine audits or inspections)
- VCU Health Policies and Procedures
    - Clinical Trial Monitor Access Flow
    - Monitor Access Option

Review/Revision History CR-RE-355		
Version No.	**Effective Date**	**Description**
CR-RE-355.3	03-14-2025	● Updated to ICH E6(R3) ● Revised monitoring definition ● Revised on-site monitoring definition ● Revised centralized monitor visit definition ● Clarified monitoring visit process ● Biennial review performed ● Minor formatting edits ● Reference links updated
CR-RE-355.2a	07-01-2020	● Links updated
CR-RE-355.2	07-01-2020	● Biennial review performed ● Minor formatting edits ● Reference links updated
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