Monitoring Visits	CR-212
Clinical Research Standard Practices	**Effective Date:** September 2024

SCOPE AND PURPOSE The document is applicable to following roles within Penn State College of Medicine and Penn State Health entities engaged in clinical research:

X	Principal Investigators	X	Regulatory Specialists
X	Sub-Investigators	X	Key Study Ancillary Personnel
X	Study Coordinators/Associates	X	Financial Analyst/Research Accountants
X	Data Specialists	X	Central Research Office Personnel

This standard operating procedure (SOP) describes the processes followed at this investigative site when the sponsor's monitor conducts a monitoring visit to:

- Assess adherence to the protocol.
- Review regulatory files for completeness.
- Ensure appropriate study drug storage, dispensing, and accountability.
- Verify data in case report forms (CRFs) with source documentation.
- Meet with the Research Nurse/Coordinator/Associate and investigator to discuss progress of the study and any concerns raised as a result of the visit.

This SOP applies to the procedures for conducting the monitoring visit for all clinical studies involving human subjects in research during all investigational phases of development. It describes the steps followed by this clinical research site from the time the monitor schedules a monitoring visit until all follow-up activities associated with the visit have been completed.

POLICY AND PROCEDURE STATEMENTS

1. Scheduling the monitoring visit
    a. Review Site Monitoring Guidelines available on the Clinical Trials Office (CTO) website.
    b. Work with the study monitor to schedule a mutually convenient date and time to conduct the monitoring visit.
        i. Remember that Investigational Drug Services (IDS) needs at least two weeks advance notice.
        ii. Check with IDS even if the monitor says they do not need to visit, as IDS may have questions for the monitor or drug that needs to be collected. Refer to Hershey Medical Center Pharmacy Administration Manual Policy Number 1414
    c. Require formal confirmation of monitoring visit via email, ideally two weeks in advance of the scheduled visit.
    d. For on-site monitoring, reserve a dedicated space for period of time needed to complete monitoring visit. This should be a quiet, private, secure space away from clinical areas. Ensure the room has internet and appropriate IT access.

e. For remote monitoring, the study team and Monitor should agree which video conferencing platform to use, ensuring it is HIPAA-compliant and supported by both organizations for the purposes of sharing personally identifiable data.
    i. Penn State **Health** Microsoft Teams and Zoom (pshealth.zoom.us) are HIPAA-complaint
    ii. Penn State **University** Microsoft Teams and Zoom (psu.zoom.us) are **NOT** HIPAA-complaint.
f. For electronic document sharing, a web/cloud-based platform may be use, but it must be HIPAA-compliant. Downloading of documents by the monitor must limited to platforms that creates an audit trail of download activity, and the monitor's is restricted to only download documents that do **not** contain PHI.
    i. Penn State's instances of Florence eBinders is the preferred platform for electronic document sharing.
    ii. Penn State **Health** Microsoft OneDrive, SharePoint, and Teams are acceptable platforms.
    iii. The platform(s) being used must be included on the HRP-598 as part of the study's IRB submission.
g. Allow time during visit for PI and Research Coordinator(s) to spend time with monitor to discuss any study related issues.
h. Follow instructions on the CTO website to request the monitor electronic medical record (EMR) access well in advance of the monitoring visit.
    i. HIPAA, Privacy, and Cybersecurity training is required to be granted EMR access. If the monitor has not yet completed the necessary training (i.e.,), screensharing with monitor is **prohibited**.
    ii. The individual screensharing PHI assumes full responsibility for ensuring the necessary training is completed.

2. Preparing for the monitoring visit
    a. Ensure that all regulatory documentation and that case report forms are complete and available for review.
    b. Ensure that all data queries received to date have been resolved to the extent possible.
    c. Ensure that the appropriate patient medical records are accessible for review at the time of the monitoring visit.
    d. Prior to a remote monitoring visit, the monitor will need to provide a list of all documentation they wish to review.
    e. Remind the study pharmacist of the scheduled visit so that study drug storage and drug accountability records can be prepared for review, if applicable.

3. Managing the monitoring visit
    a. For on-site monitoring, study team member is to ensure that the monitor signs the visit monitoring log.
    b. For remote monitoring:
        i. The monitor must not record or take screenshots during the visit.
        ii. The Monitor must only view the screen, shared during the session, in a confidential environment.

iii. The study team should only display documentation during the monitoring session that has been requested in advance by the Monitor
iv. Confidential patient information may only be shared with the Monitor if this has been addressed in the patient information sheet and consent form.
v. Confidential information should be redacted if consent for it to be shared has not been given.
vi. The study team assisting with the monitoring session must remain online at all times. If breaks are involved during remote monitoring, all devices must be logged off securely.

c. Ensure that the study monitor has all documents required to complete the monitoring visit.
d. Provide the monitor with an update on any study-related issues.
    i. Provide monitor with copies of all necessary documents for the Trial Master File maintained by Sponsor. The monitor is **not** to make their own copies of documents.
e. At the conclusion of the visit, the study team members should discuss with the monitor any issues related to:
    i. Adherence to the protocol,
    ii. Review of the regulatory files,
    iii. Verification of data in the CRFs with the source documentation,
    iv. Study drug storage, dispensing and accountability requirements for data storage.
f. Discuss any budget issues that are outstanding and progress is not being made through the budget contact at Sponsor/CRO, if necessary.

4. Following-up after the monitoring visit
    a. PI to sign any reports or correspondence left by monitor at end of visit.
    b. Upon receipt of the monitoring report/letter sent by the Sponsor/CRO:
        i. Ensure accuracy of content and any findings, and resolve any discrepancies with the monitor
        ii. Ensure that all issues identified for resolution or follow-up at the monitoring visit are addressed.
        iii. Send report/letter to PI to review and obtain signature and date.
        iv. Submit a copy of the monitoring report/letter to IRB, if appropriate.
        v. File all appropriate documentation from monitoring visit in regulatory binder.

RELATED POLICIES AND REFERENCES

Code of Federal Regulations: Investigational New Drug Application (21 CFR 312.50, 56, 59, 60, 62, 64, 66, 68)

Compliance Program Manual, Bioresearch Monitoring Program, Sponsors and Contract Research Organizations (Program# 7348.810); U. S. Food and Drug Administration; 15 September 2021

Compliance Program Manual, Bioresearch Monitoring Program, Clinical Investigators and Sponsor-Investigators (Program# 7348.811); U. S. Food and Drug Administration; 22 July 2020

Oversight of Clinical Investigations - A Risk-Based Approach to Monitoring, Guidance for Industry. *August 2013* (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/oversight-clinical-investigations-risk-based-approach-monitoring)

International Conference on Harmonization Good Clinical Practice E6(R2)

Clinical Research Guidebook (https://research.med.psu.edu/research-support/guidebook/)

Code of Federal Regulations: Institutional Review Boards (21 CFR 56.109 & 111)

Responsibilities of the Research Team (CR-102)

Site-Sponsor/CRP Communications (CR-301)

Use of Florence eBinders for Electronic Records (CR-406)

Penn State Health Policy A-65 HAM - Vendor Representative Visitation and Solicitation to Clinical and Non-Clinical Work Areas

PSH IS https://infonet.pennstatehershey.net/web/it/collaboration-and-storage

APPROVALS

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HISTORY OF REVIEWS AND REVISIONS

February 2024	
Scope and Purpose	Entities removed as all research at Penn State Health facilities are required to follow the policies and SOPs of College of Medicine is Updated "Financial Analyst/**Contract Management Accountants**". Added "Regulatory Specialists" and "Central Research Office Personnel." Notation made that this SOP may be shared with Sponsors and/or CROs upon request.
Policy and Procedure Statements	Subsection "Collecting, filing and storing study-related documents and records" renamed to "General standards." Subsection "Electronic" renamed to include "maintenance of files." Subsection "Sponsor/CRO-provided electronic Trial Management File (eTMF)" added. Florence eBinders referenced.
Approvals	"Authorized" and "Approved" switched to align with CR-101.
History of Reviews and Revisions	Section added.