Study Monitoring Visits

Process for Access to Information and Reporting of Site Visit Results

SOP HSP-0018

VA Northeast Ohio Healthcare System
Cleveland, Ohio 44106

Service Line(s):
Research Service

Signatory Authority:
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Effective Date:
November 17, 2022

Responsible Owner:
Education and Policy Specialist

Recertification Date:
November 17, 2027

1. PURPOSE AND AUTHORITY

a. To outline the process for study monitors to conduct study site monitoring visits for research conducted within the VA Northeast Ohio Healthcare System (VANEOHS).

b. Study monitors are required to comply with the VHA policies when conducting study stie monitoring visits for research conducted at the VANEOHS.

2. PROCEDURES

a. Upon notification from the study monitor, the PI and/or research staff must notify the RCO/RCA of the monitoring visit.

b. Upon arrival to the VANEOHS, the study monitor must report to the Research Office and sign-in.

c. During each monitor visit, the study monitor will be informed of the requirement to report any potential or actual serious findings to the investigator and the RCO/RCA during an exit interview.

d. Findings at the exit interview may include, but are not limited to:

(1) Suspicions or concerns that serious non-compliance may exist

(2) Findings of serious non-compliance with the study protocol, Institutional Review Board (IRB) requirements or applicable regulations and policies (e.g., failure to consent subjects, entering subjects who do not meet entrance criteria into protocols, failure to report serious or unexpected adverse events).

f. Findings of serious concerns found during the monitoring visit will be appropriately addressed by the RCO/RCA. The RCO/RCA will notify appropriate officials and committees, and other administrative entities.

g. Should there not be any serious findings or concerns, the research staff may forgo the exit meeting with the RCO/RCA, but a written notification must be submitted to the RCO/RCA indicating that there were no such findings identified by the study monitor.

h. Formal monitoring reports must be submitted to the IRB for review.

3. ASSIGNMENT OF RESPONSIBILITIES

a**. Associate Chief of Staff for Research & Development (ACOS/R).** The ACOS/R is responsible for the day-to-day operations of the research program.

b. **Research Compliance Officer (RCO) and/or Research Compliance Auditor (RCA)**. The RCO/RCA is responsible for:

(1) Meeting with the PI and/or research staff with the study monitor at the conclusion of the monitoring visit.

(2) Ensuring that the study monitor provides a verbal report of the study monitoring findings.

(3) Ensuring that the study monitor signs the "VA Research Study Monitoring Report (Appendix A)."

(4) Notifying appropriate facility officials, committees, and other appropriate administrative entities of any findings of serious concern.

(5) Maintaining a copy of all study monitor reports.

c. **Principal Investigator.** The Principal Investigator (PI) is responsible for:

(1) Meeting with the study monitor(s) prior to the monitors' beginning their work.

(2) Ensuring that the RCO/RCA is notified of all study monitor visits.

(3) Ensuring that the study monitor meets with the RCO/RCA at the conclusion of the visit.

(4) Ensuring that all contracts with pharmaceutical companies define the role of study monitors consistent with this Policy.

d. **Research Staff:** The research staff is responsible:

(1) Notifying the RCO/RCA in writing of all study monitoring visits including visits by pharmaceutical companies or CROs as soon as possible. If the monitoring visit is unscheduled or scheduled with short notice, initial communication may be by telephone.

(2) Ensuring that the study monitor meets with the RCO/RCA at the conclusion of the visit.

c. **Study Monitor:** The study monitor is responsible for:

(1) Signing in as a visitor at the research office and providing a verbal or written report to the RCO/RCA at the conclusion of the monitoring visit.

(2) Ensuring that study data recorded on the CRFs is a complete and accurate representation of the study events as verifiable from source documents.

(3) Signing the "VA Research Study Monitoring Report (Appendix A)."

If the RCO or RCA are not available, the Administrative Officer (AO) Research will meet with the study monitor at the conclusion of the monitoring visit.

4. DEFINITIONS

Study Monitor: A study monitor (also called a Clinical Research Associate (CRA), a Monitor, a Clinical Monitor, a Trial Monitor, or a Medical Monitor) is a professional who, regardless of job title, monitors the administration and progress of a clinical trial on behalf of a sponsor. The sponsor, whose intent is the research of pharmaceuticals, biologics, and/or devices, may employ these individuals either directly or indirectly (via Contract Research Organizations (CROs) or independent consultants/contractors). The study monitor must be independent of the investigative staff conducting the research at the site or institution and should not be employed or supervised by the investigative site or the institution.

b. **Sponsor:** A person who takes responsibility for and initiates a clinical investigation. The sponsor may be an individual or pharmaceutical company, governmental agency, academic institution, private organization, or other organization. The sponsor does not actually conduct the investigation unless the sponsor is a sponsor-investigator. A person other than an individual that uses one or more of its own employees to investigate that it has initiated is a sponsor, not a sponsor-investigator, and the employees are investigators (21 CFR 312.3).

c. **Contract Research Organization (CRO):** A person (or entity) that assumes, as an independent contractor with the sponsor, one or more of the obligations of a sponsor, e.g., design of a protocol, selection or monitoring of investigations, evaluation of reports, and preparation of materials to be submitted to the Food and Drug Administration.

d. **Monitoring:** A sponsor of clinical studies is obliged by law to monitor all ongoing clinical studies. Monitoring is usually performed during routine visits to the study site. FDA regulations (21 CFR 312.56) and ICH Guidelines ICH-E6 5.18 identifies three purposes for study monitoring:

(1) To verify that study subjects' rights are protected.

(2) To ensure that study data recorded on the case report form (CRF) is a complete and accurate representation of the study events as verifiable from source documents.

(3) To validate that the study is being conducted according to GCP and the protocol is being adhered to.

5. REFERENCES

a. ORD Guidance on Remote Monitoring of VA Clinical Trials by External Monitors Using the Webex Collaboration Technology Sharing Platform
https://www.research.va.gov/resources/policies/guidance/Clinical-Trials-Webex.pdf

6. REVIEW

At recertification or when there are changes to the governing documents.

7. RECERTIFITION

This SOP is scheduled for recertification on or before the last working day **of November 17, 2027.** In the event of contradiction with national policy, the national policy supersedes and controls.

8. SIGNATORY AUTHORITY

Neal Peachey 411157

Digitally signed by Neal Peachey 411157
Date: 2022.11.25 09:44:10 -05'00'

Neal Peachey, Ph.D.
Associate Chief of Staff/Research
Date Approved: November 17, 2022

NOTE: *The signature remains valid until rescinded by an appropriate administrative action.*

DISTRIBUTION: This will be posted on the Research website:
https://www.clevelandvaresearch.org/