

**LOUIS STOKES CLEVELAND VA MEDICAL CENTER
RESEARCH SERVICE
Human Subject Protection
Standard Operating Procedure (SOP)**

Effective Date: September 5, 2019

SOP Title: Study Monitoring Visits - Process for Access to Information and Reporting of Site Visit Results

SOP Number: HSP-018

SOP Version: .05

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

2. **POLICY:** Study monitors are required to comply with VHA policies when conducting study site monitoring visits for research conducted at the VANEOHS.

3. **DEFINITIONS:**

a. **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 conduct an investigation 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.

4. 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)."

In the event that the RCO or RCA is not available the Administrative Officer (AO) Research will meet with the study monitor at the conclusion of the monitoring visit.

5. 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.

6. STUDY MONITOR ACCESS TO SOURCE DOCUMENTS

a. Computerized Patient Record System (CPRS) access may not be granted directly to the study monitor and individual or personal VA computer access codes are not to be

shared for any reason.

b. To ensure that VA patient confidentiality and Health Insurance Portability and Accountability Act (HIPAA) regulations are maintained, study monitors will be allowed to view CPRS information only when the subject has signed a HIPAA compliant authorization and under the direct supervision of the PI and/or study staff.

c. The study monitor can view source documents using the VA Employee Driver Method. This method involves a VA employee "driver" accessing the system with the study monitor watching and shows the study monitor only information that the study monitor needs and is authorized to see for the specific study.

d. Please note that a full background check and VA training is required to gain full access to VHA computer systems.

7. **REFERENCE:** VHA Memorandum "Reporting of All Study Site-Monitoring Visit Results" dated October 14, 2004 and 21 CFR 312.3. VHA Memorandum "Clinical Trial Monitor Access" dated April 24, 2008."

8. **RESCISSION:** The rescission date for this procedure is September 4, 2022.

9. **FOLLOW-UP RESPONSIBILITY:** Research Administrative Officer



VA Research Study Monitor Report

Date:

Study Name:

Was this visit-pre arranged? NO YES, **if Yes**, how: phone e-mail previous visit

What is the reason for this visit?

Who was consulted during the review? (List names below)

Principal Investigator:

Study Coordinators:

Pharmacist:

Other staff:

Was there any protocol deviations noted during the monitoring visit?

None Minor, Major, Serious

(IF Yes to major or serious, summarize findings that must be addressed or attach a copy of findings)

Will a follow-up report be sent? NO YES

Signature of monitor: _____

Print Name of monitor: _____

Signature of Research Compliance Office Personnel: _____

Print Name (Research Compliance Office Personnel): _____

Do you have an anticipated date of next visit? NO YES, **if yes** date _____