

LOUIS STOKES CLEVELAND VA MEDICAL CENTER  
Medical Research Service  
Institutional Review Board  
SOP Cover Page

Effective Date: July 1, 2005

SOP Title: Reporting of All Study Monitoring Visit Results

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 \_\_\_\_\_ July 1, 2005  
Signature Date

Approved By:

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Signature Date

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Signature Date

**LOUIS STOKES CLEVELAND VA MEDICAL CENTER  
RESEARCH SERVICE  
Institutional Review Board  
Standard Operating Procedure (SOP)**

**Effective Date:** July 1, 2005

**SOP Title:** Reporting of All Study Monitoring Visit Results

**SOP Number:** HSP-015

**SOP Version:** .00

1. **PURPOSE:** To provide for notification to the appropriate Louis Stokes Cleveland Department of Veterans Affairs Medical Center (LSCDVAMC) research staff of site monitoring visits and to have them be informed of any serious findings or issues of concern that result from the monitoring visits.
2. **POLICY:** Study monitors must check in and out with the Research Office while conducting a site visit.
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 CROs or independent consultants/contractors). The 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.
  - c. **Contract Research Organization:** 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 identify three purposes for study monitoring:
    - (i) To verify that study subjects' rights are protected.
    - (ii) 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.

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

4. **RESPONSIBILITIES:**

- a. **Principal Investigator:** The Principal Investigator (PI) is responsible for meeting with the study monitor(s) prior to the monitors' beginning their work.
- b. **Research Staff:** The research staff is responsible for notifying the Research Compliance Officer (RCO) of all monitoring visits by pharmaceutical companies or CROs as soon as possible.
- c. **CRO or Monitor:** The CRO or monitor is responsible for signing in as a visitor at the research office and providing a verbal or written report to the RCO or Administrative Officer (AO) at the conclusion of the monitoring visit.

5. **PROCEDURES:**

- a. Upon notification from the CRO or monitor, the research staff must notify the RCO of the monitoring visit.
- b. Upon arrival to the LSCDVAMC, the monitor must report to the Research Office and sign-in.
- c. During each visit, the role of the monitor should be reviewed, including the new requirement that any potential or actual serious findings be conveyed to the investigator and the RCO or AO during an exit interview.
- d. Findings at the exit interview may include, but are not limited to:
  - (i) Any suspicions or concerns that serious non-compliance may exist, and
  - (ii) All 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).
- e. Should there be findings of serious concerns found during the monitoring visit, these will be appropriately addressed by the RCO and the appropriate officials and committees will be notified as required by Medical Center and/or Medical Research Policy.
- f. Should there not be any serious findings or concerns, the research staff must notify the RCO or AO in writing that there were no such findings identified by the monitor.
- g. Monitoring reports must be submitted to the IRB at the time of continuing review.

6. **REFERENCE:** VHA Memorandum dated October 14, 2004 and 21 CFR 312.3.

7. **RESCISSION:** The rescission date for this procedure is June 30, 2008.

8. **FOLLOW-UP REPONSIBILITY:** Research Compliance Officer