Department of
Veterans Affairs

Memorandum

Date: OCT 14 2004

From: Acting Chief Research and Development Officer (12)

Subj: Reporting of All Study Site-Monitoring Visit Results

To: Network Directors (10N1-23)

Thru: Acting Deputy Under Secretary for Health (10A)

Thru: Deputy Under Secretary for Health for Operations and Management (10N)

1. Many of the research studies conducted at VA facilities are monitored by entities externa to that facility, e.g., pharmaceutical companies and Contract Research Organizations (CROs through site visits. These site visits may be routine or conducted for specific causes. It is imperative that the appropriate research staff is notified of these visits and informed of any serious findings or issues of concern that result from the monitoring visits. To ensure that this occurs, this memorandum outlines issues that must be addressed and procedures that must be implemented. Please share the following information with your Associate Chiefs of Staff for Research and Development (ACOS/R&D).

2. The following guidance is applicable for each study that is monitored by a pharmaceutical company or CRO.

a. The ACOS/R&D or his/her designee is to be notified of all monitoring visits by pharmaceutical companies or CROs as soon as possible. This is the responsibility of the research staff person who schedules or confirms the monitoring visit. If the monitoring visit is unscheduled, the ACOS/R&D is to be notified as soon as the study personnel are aware of the visit.

b. The CRO or study monitor must sign in as a visitor at the research office as required of all visitors to research areas.

c. The Principal Investigator or other responsible investigator is to meet with the study monitor(s) prior to the monitors' beginning their work. During each visit by a monitor, 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 ACOS/R&D, Administrative Officer for Research (AO/R&D) or his/her designee during an exit interview. Findings that require an exit interview include but are not limited to:

(1) Any suspicions or concerns that serious non-compliance may exist, and

(2) 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).

d. If the monitor records no serious findings or concerns as listed above, the study investigator or research coordinator must notify the research office in writing that there were no such findings identified by the monitor.

3. Each research office must develop procedures that will ensure all serious findings and concerns found during the monitoring visit are appropriately addressed and the appropriate facility officials and committees are notified as required by facility policy. These procedures must also require that monitoring reports be submitted to the IRB at the time of continuing review.

4. Contracts with pharmaceutical companies must define the role of study monitors that is consistent with the requirements of this memo.

5. If you have any questions concerning this policy, please contact Brenda Cuccherini, Ph.D. in the Office of Research and Development at (202) 254-0277.

Stephan D. Fihn, MD, MPH

cc: ACOS for Research (151)
Medical Center Directors (00)