

## PROCEDURE FOR EXTERNAL MONITORING VISITS Atlanta VAMC

Monitors/Clinical Research Associates (CRA), auditors, and any other authorized external entities representing the study sponsor are required to complete the Privacy and HIPAA Training and VA Privacy and Information Security Awareness and Rules of Behavior prior to having access to the research participant's Protected Health Information (PHI). This training must be done annually.

- Prior to the monitoring visit, the PI (Principal Investigator) and/or Research Coordinator will provide the monitor with the instructions for the Privacy and HIPAA Training and VA Privacy and Information Security Awareness and Rules of Behavior

**NOTE:** For detailed instructions, please see **“VHA Privacy Policy Training Instructions for Monitors”** found at <http://www.atlaref.org/forms/vamc.cfm> under the section titled: VA Human/Clinical Studies Forms

- The Monitor is responsible for providing a copy of the privacy training certificates of completion to the PI and/or Research Coordinator and the Clinical Studies Center (CSC) Administrative Assistant prior to accessing PHI
- The PI and/or Research Coordinator is responsible for reporting monitoring visits prior to or at the commencement of the scheduled visit by completing the **“Monitoring Visit Report - Entrance Briefing”** form and faxing it to the Clinical Studies Center at (404) 417-2991. This form can be found on the AREF website. If it is a “for cause” audit, the CSC will forward the form to the Research Compliance Officer (RCO)
- The person conducting the monitoring visit and/or audit should exhibit proof of their authorization by showing a company or photo ID
- An exit interview with the Monitor, PI, Research Coordinator, and RCO is required if the study is a VA Cooperative Study, if the visit is a “for cause” audit, or if non-compliance or other serious problems were identified during the monitor's visit. Please contact the RCO immediately by telephone (ext. 6964) or the RCA (ext. 3452), if any issues are found and/or an exit interview is required. Findings that require an exit interview include but are not limited to:
  - Any suspicions or concerns that non-compliance may exist
  - Serious non-compliance with the study protocol, Emory Institutional Review Board (IRB)/VA Research requirements, or applicable regulations and policies such as:
    - Failure to consent subjects prior to initiating study activities
    - Enrolling subjects who do not meet study inclusion criteria
    - Failure to report unanticipated serious adverse events or unanticipated problems
- The PI and/or Research Coordinator is responsible for completing the **“Monitoring Visit Report - Exit Briefing”** form and faxing it to the CSC at the completion of the

monitor's visit. This form can be found on the AREF website. A copy of this form should be kept in the regulatory binder.

- The research study team should inform monitors prior to the visit that the VA does not have internet access available for their use. It is recommended that the monitors bring their own internet access card.
- Contact the Clinical Studies Center (CSC) in advance if a work area is needed for the monitoring and/or audit site visit.