Clinical trial monitors affiliated with sponsors or staff from regulatory agencies or review bodies such as the IRB, are often responsible for monitoring the progress of a clinical trial, which may include reviewing source documents to verify adherence to the Institutional Review Board (IRB) and Research & Development (R&D) Committee approved research study.

1. **Entrance Form:** 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 (CSC) at (404) 417-2991 or delivering it directly to or emailing it to the CSC Manager or Assistant. This form can be found on the AVAHCS research website. If it is a “for cause” audit, the CSC will forward the form to the AVAHCS Research Compliance Officer (RCO).

2. **Exit Form:** The PI and/or Research Coordinator are responsible for completing the “Monitoring Visit Report Exit Briefing” form and sending it to the Clinical Studies Center Manager at the completion of the monitor’s visit. This form can be found on the AVAHCS research website. A copy of this form should be kept in the regulatory binder.

3. **Exit Interview:** An exit interview with the Monitor, PI, Research Coordinator, RCO and/or RCA 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.

   I. 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, 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
   
   II. If an exit interview is indicated, immediately contact the following AVAHCS Research Staff:
      - AVAHCS Research Compliance Officer Rodney Thompson at ext. 206964 or rodney.thompson2@va.gov
      - AVAHCS Research Compliance Auditor
      - Jane Guidot, CSC Manager at ext. 206933 or jane.guidot@va.gov

4. **Monitoring Methods:** Monitoring must be done using one of the following methods:

   I. **Atlanta VAHCS Employee Driver Method — preferred method:** An AVAHCS study team member is present while monitor reviews CPRS and/or paper records. The monitor only has access to research subjects’ information.
associated with the research project and is supervised by the study team throughout the visit. If accessing CPRS, the AVAHCS study team member logs in, opens the appropriate screens in CPRS, and is present during the review of CPRS. Monitors are not allowed unsupervised access to CPRS.

a) Requirements:
   i. Study staff verifies that the IRB approved ICF/HIPAA form lists the sponsor or regulatory entity that is performing the monitoring.
   ii. TMS Courses “VA Privacy and Information Security Awareness and Rules of Behavior” and “VHA Privacy and HIPAA Training” certificates are not required.

II. Read-Only Access method for non-VA employees (not recommended): Monitors will be permitted to have “read-only” access to CPRS. The monitor will be able to select for viewing any of the documents in CPRS that relate to a given study subject without the supervision of a study team member.

a) Requirements:
   • 2 weeks prior to monitoring visit study team contacts:
     o Clinical Studies Center Manager and provides rationale for request
     o Clinical Applications Coordinator (CAC) who will create Order Entry/Results Reporting List (patient list)
     o AVAHCS Research Training Coordinator for CPRS username and password assignment for monitor
     o Privacy Office who will grant permission to access PHI in CPRS
   • Provide copy of annual TMS training certificates to CSC office staff:
     o VA Privacy and Information Security Awareness and Rules of Behavior
     o VHA Privacy and HIPAA Training
     o See VHA Privacy Policy Training Instructions for Monitors on the AVAMC research website
   • Provide Monitors Social Security number

III. Read-Only Access method for VA employees (i.e.; Smart Team):
   a) Requirements: Check-in at the Clinical Studies Center

5. Internet: The research study team should inform monitors prior to the visit that the VA may not have internet access available for their use. It is recommended that the monitors bring their own internet access card.

6. Monitor Station: Contact the Clinical Studies Center in advance if a work area is needed for the monitoring and/or audit site visit.