STANDARD OPERATING PROCEDURES
Clinical Trial Monitor Access to Study Participant Records in CPRS

Clinical trial monitors are responsible for verifying that VA research trials are conducted in accordance with FDA requirements and must review pertinent medical records in the Computerized Patient Record System (CPRS). The VA Office of Information and Technology (OI&T) has approved two methods to provide clinical trial monitors access to pertinent source documents located in the electronic medical records of VA study subjects. CPRS access given to monitors must minimize risks to the VA's data system and protect the privacy of veterans who have not given signed authorization permitting access to their records.

1. Establishment of clinical patient groups in CPRS

    a. The IRB Program Support Assistant will establish a clinical patient group involving only consented study subjects within CPRS for each sponsored clinical trial.

    b. When a participant is enrolled in a study, the study coordinator will send a copy of the signed consent to the IRB Program Support Assistant, who will enter the new name into the CPRS list to keep the list current.

2. Notification of Planned Monitor Visit

    A member of the study team will notify the IRB Program Support Assistant, who has been designated to receive notifications for the Associate Chief of Staff for Research (ACOS/Research), of the planned visit one week prior to the date of the visit via e-mail or hard-copy. The IRB Program Support Assistant will notify the Research Compliance Officer of the planned visit.

3. Verification of HIPAA Authorization

    a. Before granting the monitors access to study participants' medical and research records, the Privacy Officer (PO) will assure there is a signed HIPAA authorization for the release of the information.

    b. To accomplish this, at least a week prior to the monitor visit, a member of the study team will provide the PO with a list of current study participants and copies of their signed HIPAA authorizations for verification. The PO will sign a verification form to document this process.

4. Clinical Trial Monitor Access

    a. Method #1: Limited Read-only Access to Selected Data in the Electronic Health Record (EHR)
    This method provides for direct access for the monitor to a limited read-only set of patient records for a specific study. The advantage of the limited read-only access approach is that

the monitor will be able to select for viewing any of the documents in CPRS that relate to a given study subject. A complete and un-redacted copy of that subject's health information will be available. The disadvantage of this approach is that an individual unfamiliar with CPRS is likely to find it difficult to navigate efficiently to the desired documents.

Prior to granting access the following requirements must be completed:

i. Monitors are required to sign the National Rules of Behavior document (available on the IRB forms SharePoint site- Clinical Monitor Procedures folder).

ii. Monitors must complete VA Privacy and Information Security Awareness and VHA Privacy Policy Web training. The courses must be completed before access to the VA information system(s) is granted and annually thereafter.

The courses can be accessed directly through the VA Learning Management System (LMS) at https://www.lms.va.gov. Users without an LMS account (e.g. short term contractors) can access the course at https://www.ees-learning.net/librix/loginhtml.asp?v=librix. Where users cannot take the mandated training via the LMS, acceptable alternative methods have been established and the study team should contact the Program Support Assistant in Research Service (x2800) for more information.

iii. Monitors must provide their social security number (SSN) to the ADPAC for Research Service. CPRS and the Veterans Health Information Systems and Technology Architecture (VistA) use SSNs as a unique identifier. VA agrees not to use SSNs for any other purpose other than for the creation of the accounts. The user accounts will be set up to purge the SSNs from CPRS at the end of the session.

iv. A member of the study team will notify the Research Service ADPAC one week in advance of a monitor's visit and provide the ADPAC with evidence of completion of required training, the monitor's Social Security Number and date of the monitor visit.

v. Upon their arrival, monitors will sign-in at the Research Office according to the procedures described in Section 5, below.

b. Method #2: Employee Driver Method

The VA Employee "driver" accesses the system with the monitor watching and shows the monitor only the information that the monitor needs and is authorized to see for the specific trial. The advantage of this approach is that the VA employee will be able to efficiently navigate to the documents that the monitor wishes to view. The disadvantage of this approach is that the monitor cannot independently verify that all of the relevant data on a subject was reviewed. Monitors will sign-in at the Research Office according to the procedures described in Section 5, below.

5. Clinical Monitor Check-in/Check-out Procedures

a. Upon their arrival, monitors will be accompanied by a study team member to sign-in at the Research Office and will be issued a temporary visitor badge. Both the monitor and a study team member will sign the logbook at the beginning and end of the visit. The monitor will wear the badge throughout the visit and return it to the Research Office and sign out at the close of each day.

b. Exit interviews with the monitor and the RCO and/or ACOS/R are recommended for routine findings, but are required if evidence of serious non-compliance is identified.

6. Access for Multi-site Clinical Trials, Involving a VA Principal Investigator

For multi-site clinical trials involving a VA principal investigator (e.g. VA, National Institutes of Health (NIH), or an industry sponsored study), read-only access of a clinical patient group can be provided through the Compensation and Pension Record Interchange (CAPRI) tool. This process will be managed centrally through the Office of Health Information, Health Information Access (HIA) team (email:VHA 19 HDI HIA).

REFERENCES

Memorandum from Deputy Under Secretary for Health for Operations and Management, Dated June 7, 2010. Guidance on Implementation for Approved Methods for Clinical Trial Monitor Access.