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ORD Guidance on Remote Monitoring of VA Clinical Trials by External Monitors Using the Webex Collaboration Technology Sharing Platform

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This is a new guidance document.

For questions on the content of this guidance, email the VHA Office of Research and Development through FIND Pro.

Background:

Clinical trial monitors (commonly referred to as monitors) are responsible for monitoring the progress of the clinical trial, including information in the VA subject's electronic health record (EHR) as applicable to the clinical study activity as well as other documents required for review to verify that (1) subject data collected and obtained for the clinical study are accurate and complete, (2) the VA Investigator is adhering to the approved protocol, and (3) regulatory requirements, including applicable Institutional Review Board (IRB) approvals and reporting of protocol required events to the IRB and sponsor, are completed.

On June 7, 2010, the Deputy Under Secretary for Health for Operations and Management issued the VA Memorandum titled, "Guidance on Implementation of Approved Methods for Clinical Trial Monitor Access". This VA Memorandum described methods that can be used to protect data within a patient's EHR while allowing monitors appropriate access to the records through use of the VA employee driver method. In the employee driver method, a VA employee "driver" accesses the system with the monitor watching; the monitor is only shown the information that the monitor needs and is authorized to see for the specific trial.

As a result of the COVID-19 pandemic, some methods used to conduct periodic monitoring of clinical trials in VA by external monitors may not be practicable. Prior to the COVID-19 pandemic, the majority of monitoring visits by external monitors involved monitors physically traveling to the VA Facility where the VA research personnel were located. In response to the COVID-19 pandemic, VHA personnel engaged in VA approved research are permitted to use non-public facing remote audio or video communication technology outside of VA network systems as described in the 10X Memorandum dated April 7, 2020: Use of Video Communication Technology for VHA Research and Development Activities Under COVID-19 located on the ORD COVID-19 SharePoint at https://dvagov.sharepoint.com/sites/vacovhacomm/admin/projects/covid19/SitePages/ORD-Communications.aspx. Skype, Web-Ex, and Microsoft Teams are three methods used within VA Facilities to initiate video conferences. These same technologies can be used to conduct "remote monitoring visits" when the monitor is not physically present at the VA facility using the employee driver method.

This guidance document describes suggested practices that can be used by VA Facilities to facilitate the conduct of remote monitoring visits by external monitors for VA clinical trials. This document does not represent a single set of implementation practices that must be used in the exact order or sequence provided in this guidance document; alternative implementation practices can be used if they are

consistent with reducing the risk to VA records and systems and meet applicable regulatory requirements.

Scope:

This guidance document is an implementation guide for the use of Webex to conduct remote monitoring for clinical trial monitoring by external monitors (non-VA employees) requiring access to protected health information and the Electronic Health Record (EHR) using a VA employee as the driver of the documents. There are other types of VA-approved collaboration conference sharing platforms that could be used to conduct remote monitoring, including Skype and Microsoft Teams which will not be addressed in this guidance document. This guidance should not be interpreted as presenting a position by ORD that all monitoring for clinical trial monitoring must be conducted remotely. This guidance document is also not intended to apply to monitors and auditors who are VA employees or are under contract to the VA to provide these services and have completed required background checks and obtained VA PIV cards to have access to VA's EHR.

The following suggested sequence of steps taken prior, during, and following a remote monitoring visit will be addressed in this guidance document:

1. Equipment and Access Requirements to Conduct a Remote Monitoring Visit
2. Verifying Regulatory Requirements Prior to Scheduling the Remote Monitoring Visit
3. Scheduling the Remote Monitoring Visit
4. Testing the Equipment Used to Conduct a Remote Monitoring Visit
5. Preparing (Staging) Documents for Review
6. Conducting the Remote Monitoring Visit: Record Review
7. Ending the Remote Monitoring Visit

1. Equipment and Access Requirements to Conduct a Remote Monitoring Visit

To facilitate a remote monitoring visit, VA research personnel must have access to equipment and the EHR in addition to setting up an individual Webex account. The following is a list of suggested equipment and access requirements:

- A VA research team member must have access to VA's EHR through CPRS/VISTA or Joint Legacy Viewer (JLV).
  - Either CPRS/VISTA or JLV can be used for remote monitoring visits. Some VA research personnel find JLV to be easier to navigate than CPRS/VISTA. The VA research team member should become proficient with navigating CPRS/VISTA or JLV prior to the remote monitoring visit if new to using VA's EHRs. Detailed training on JLV can be found within the JLV platform: https://jlv.med.va.gov/JLV/app.

- A VA research team member must have access to a VA computer with internet capabilities.
- Camera capability is recommended either on the computer or through use of a web camera to be able to view the clinical trial monitor (and allow the clinical trial monitor to view the VA research team member).
- It is recommended that only one VA research team member be responsible for managing the computer during the monitoring visit. If interactions with other site personnel are required during a virtual meeting, the VA research team member who is designated as the responsible individual for the visit must retain control of the computer.
- The VA research staff member who will be facilitating the remote monitoring visit must set up a VA Webex account at https://veteransaffairs.Webex.com/.
    - The VA research team member does not need to set up a separate VA Webex account for remote monitoring.
    - It is recommended that VA research staff members review and take Webex training to increase proficiency with its use. Webex resources are located at the Webex Meeting resource page: https://dvagov.sharepoint.com/sites/OITUCIS/Webex/SitePages/Webex.aspx
- The research staff member should also become proficient in the use of other software applications, such as MS Word, MS Excel, and Adobe Acrobat for documents that will be viewed using these tools.

2. Verifying Regulatory Requirements Prior to Scheduling the Remote Monitoring Visit

A VA research team member cannot initiate a monitoring visit without verifying that the applicable regulatory requirements are met to allow a monitoring visit to occur. This is not unique to remote monitoring; this applies to any clinical monitoring visit. Both privacy and informed consent regulatory requirements must be verified prior to scheduling the remote monitoring visit prior to initiation of any monitoring visit as follows:

- Consistent with the VA Memorandum titled, "Guidance on Implementation of Approved Methods for Clinical Trial Monitor Access", the VA research team member must ensure that the signed HIPAA authorizations specifying the disclosure of protected health information (PHI) to clinical trial monitors for the subjects whose records are to be monitored permit access to the records. Clinical trial monitors cannot be granted access to VA subjects' PHI if a signed, valid HIPAA authorization cannot be produced.
- The VA subjects' signed and dated informed consent documents do not prevent access by the clinical trial monitors to the subject's PHI.
- Verification of the regulatory requirements to allow access to the subjects' individually identifiable information (III) for purposes of the remote monitoring visit may be done by the VA research team or by another party (e.g., privacy officer) dependent upon local VA Facility requirements.
- ORD recommends that the VA research team member document that the regulatory requirements are met prior to scheduling the monitoring visit and place the documentation in the investigator's regulatory study file (not individual subject files). If a local VA Facility has specific documentation requirements, the local VA Facility documentation requirements must be followed.

3. Scheduling the Remote Monitoring Visit

Communication with the clinical trial monitor must occur as part of the process of scheduling a remote monitoring visit. VA research team members must communicate the proposed collaborative conference sharing platform that is to be used when scheduling the remote monitoring visit; VA research team members should not assume clinical trial monitors use the same conference sharing platforms used in VA. The following are recommended practices VA research team members should follow when scheduling a remote monitoring visit:

- Before scheduling a remote monitoring visit with an external monitor, the VA research team member should communicate in writing and/or orally what platform will be used (e.g. Web-Ex) and determine if the monitor has any specific requirements he/she must follow as part of a remote monitoring visit. For example, a monitor may request that the VA research staff member write an email verifying that a remote monitoring visit will be used for the study.
- Similar to any clinical monitoring visit, the VA research team member should request a list in writing to identify the subjects and records required for the record review component of the remote monitoring visit.
    - Please note that reviewing records remotely requires a longer period of time than reviewing records with the clinical trial monitor at the VA Facility. When scheduling a remote monitoring visit, allow an adequate amount of time to review the records requiring monitoring.
- The VA research team member should request if any non-subject records, such as documents from the regulatory binder, are to be provided in advance of the meeting. The VA research team member should confirm the regulatory site documents to be viewed during the session and the electronic location of those documents (to include the precise records to be reviewed such as, but not limited to, the IRB approval notifications, IRB rosters, research team member CVs, training, and pharmacy accountability documentation).
- The VA research team member should confirm if there are any outstanding issues from previous visits or data queries that are to be addressed during the planned remote monitoring visit. The VA research team member should confirm that those subject records are included in the subject list requested by the clinical trial monitor.
- The VA research team member should request a list of the study staff and other facility staff (e.g., ACOS/R, AO/R, RCO, research pharmacist) required to participate in the virtual meeting and the expectation (e.g., time of day, time required) for their participation.
- Following confirmation of the scheduled date(s) and time of the remote monitoring visit, the VA research team member should send a Webex email invitation to the clinical trial monitor a minimum of five (5) business days prior to the scheduled remote monitoring visit.
    - The VA research team member can choose to use his or her VA Webex Personal Room to conduct the monitoring visit. A Webex Personal Room is a Webex user's virtual conference space.
- VA research team should notify the VA Facility research office and other individuals (such as the VA Facility Privacy Officer) if required by local VA Facility research policies to inform them that a remote monitoring visit has been scheduled.

- VA research team members should also have a back-up plan if the session is interrupted or terminated early.

4. Testing the Equipment Used to Conduct a Remote Monitoring Visit

Part of the preparations for a remote monitoring visit include testing the equipment to be used prior to the day of the scheduled remote monitoring visit. This testing is just as important as obtaining the list of records to be reviewed during the remote monitoring visit.

- At least two (2) business days before the scheduled monitoring visit, the VA research personnel should schedule a technical test with the clinical trial monitor to ensure that they can access the platform and has the ability to view documents shared by the VA research team member.
- If the computer being used for the monitoring visit does not have a built-in camera, it is recommended that the site procure an OI&T approved web camera to facilitate the remote monitoring visit.
- This technical test can also be used to confirm the date and time of the remote monitoring visit, review the agenda, and discuss processes that will be used to conduct the visit.

5. Preparing (Staging) Documents for Review

Facilitating a remote monitoring visit usually requires more preparation than a monitoring visit occurring when the clinical trial monitor is physically present at the VA. Some records are only available in hard copy and must be scanned in preparation for electronic viewing. The process of preparing the documents for review by a clinical trial monitor is called "staging". The following are recommended practices VA research team members should use when staging documents in preparation for a remote monitoring visit:

- Based on the purpose and goal of the monitoring visit, the VA research team member should create a rough monitoring visit agenda to be used in staging. If the remote monitoring visit is to take multiple days, it is recommended that a secure shared drive folder on the VA folder of non-patient records to be reviewed and patient list be created in CPRS/VISTA or JLV for each day with the materials required only for that day.
    - Do not place the folders on a VA desktop.
- The VA research team member should always utilize computer desk hygiene to prevent accidental access to documents that are not part of the remote monitoring visit. Consideration of desk hygiene should be part of staging the documents in preparation for the remote monitoring visit.
    - Remove or file any documents, short cuts, etc., to minimize distractions and avoid inadvertent breaches
    - Close all but the specific programs that will be used in the remote monitoring visit including email.

  - Enter the information of the subjects to be viewed so that only those specific subjects appear in the recently viewed dialog box in CPRS/VISTA or JLV. This will allow the VA research team member to quickly open the needed information for the current subjects to be reviewed.
  - In the secure shared drive folder where electronic research records are stored, stage all documents and subject records that will be used in the remote monitoring visit in a folder created for that specific remote monitoring visit date(s).
- The VA research team member should scan documents that are not available electronically (e.g. informed consent documents not scanned into the EHR) and organize into electronic files or organize the paper documents so that they can be held up for viewing using the camera.
  - Scanned documents cannot be altered or modified in any way. For scanned documents, it is recommended that the VA research team member prepare a letter of certification that can be given to the clinical trial monitor verifying that the individual who scanned the document did not modify or adulterate the original document or the scanned version that is available for viewing during the monitoring visit.
- It is recommended that the VA research team member create a patient list in CPRS/VISTA or JLV to simply tasks such as reviewing subject charts.

6. Conducting the Remote Monitoring Visit: Record Reviews

When conducting a remote monitoring visit, it is important to remember that anyone communicating with the clinical trial monitor is responsible to protect subjects' privacy and confidentiality during and after a remote monitoring visit. The following are recommended practices VA research team members should take when conducting the record review portion of a remote monitoring visit:

- It is recommended that only one VA research team member be responsible for managing the computer during the monitoring visit. If interactions with other site personnel are required during a virtual meeting, the VA research team member who is designated as the responsible individual must retain control of the computer at all times.
- On the day of the remote data monitoring visit, the VA research team member who is the designated responsible individual should ensure that the following items are completed prior to the scheduled time:
  - Close all non-relevant programs to include Outlook, Instant Messaging, etc. to prevent the accidental sharing of data that is not related to remote monitoring visit.
  - If the VA research team member is running Skype, it is recommended that the VA research team member change his or her status to "Do Not Disturb" during the monitoring visit. This will prevent messages from appearing on the screen during the monitoring visit.
  - Ensure that all regulatory site documents are available via the screen and minimized until needed to be opened.

  - Ensure that all outstanding issues from previous visits or data queries that are to be addressed during the visit are available via the screen and minimized until needed to be opened.
  - Minimize any study specific "Patient Lists".
- The VA research team member should initiate the Webex meeting with screen sharing off – audio and video only on prior to verifying credentials.
- The clinical trial monitor's credentials should be verified when initiating the remote monitoring visit. This can be done by the monitor showing his or her respective identification using the camera function of the meeting or another method of verifying the monitor's credentials.
- The VA research team member and clinical trial monitor should establish the rules for the monitoring visit, e.g., describe the process to be used, review the agenda and adjust as necessary, resolve any unclear points. The VA research team member should not begin sharing the screen for review of records unless both parties are clear on the processes and goals for that day.
- The VA research team member should reinforce to the clinical trial monitor that when reviewing records in the EHR the subjects will be fully identified and no screen shots or recording of any information in any manner from the screen sharing is allowed except for purposes of the monitoring visit (e.g., notes using the subjects' study identification number findings relevant to the study).
- The VA research team member should share the screen and begin the review of the previously staged research records as outlined in the agenda
  - If additional materials (documents, additional patients in the EHR) need to be reviewed that were not part of the originally agreed to list, stop screen sharing and stage these new materials and re-start screen sharing. Update any agendas or logs that may require an update of this information.
- The VA research team member should stop screen sharing at any point in the meeting where active showing for research records is not required.
- If it is necessary for the monitor to privately communicate with other members of the site study staff other than the VA research team member who is the responsible individual, a separate method of communication – such at a phone call – should be arranged. If a separate video conference is required with other members of the study team, then such individuals must meet the same requirement as the VA research team member who is the designated responsible individual. Sharing a login account is a violation of VA policy. The VA research team member in control of the computer must be the same VA research team member logged in.
- If the virtual meeting occurs over several days, the VA research team member and clinical trials monitor should confirm the agenda for the next day so the next day's materials can be staged.

7. Ending the Remote Monitoring Visit

- Before ending the remote monitoring visit, the VA research team member should request how written observations or the written report of the monitoring visit will be sent by the monitor; this is not unique to remote monitoring visits.

- The VA research team member should select "end the meeting" (not "leave the meeting") to terminate the meeting connection once the work for the meeting is completed.
- The VA research team member should confirm that the Webex meeting has ended.
    - Note: Only the VA research team member can end the Webex meeting since it was created by him or her.
- The VA research team member should destroy any scanned documents or paper copies of electronic documents created solely for purposes of conducting the remote monitoring visit; these are not federal records and are considered to be working documents.
- The VA research team member should follow local policies and requirements, if applicable, to notify the Research Office that the virtual meeting has ended, and/or if there are follow-ups.
- The VA research team member should retain documents created or completed for the monitoring visit and file these documents with the study regulatory file.

References:

FDA Guidance: June 7, 2020: "FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency – Guidance for Industry, Investigators, and Institutional Review Boards"

VA Memorandum: June 7, 2010: "Guidance on Implementation of Approved Methods for Clinical Trial Monitor Access"

VA Memorandum: April 7, 2020: "Use of Video Communication Technology for VHA Research and Development Activities under COVID-19"

VHA Directive 1200.05: January 7, 2019 (amended March 3, 2020): "Requirements for the Protections of Human Subjects in Research"