Department of Veterans Affairs

Memorandum

Date: APR 24 2008

From: Under Secretary for Health (10)

Subj: Clinical Trial Monitor Access (WebCIMS 397373)

To: Assistant Secretary for Information and Technology (005)

1. I am writing to request your approval for Veterans Health Administration (VHA) to employ several alternative methods of providing clinical trial monitors with access to pertinent medical records of Department of Veterans Affairs (VA) study subjects. These monitors are responsible for verifying that VA research trials are conducted in accordance with Federal Drug Administration requirements and must review pertinent study records to do so. The monitors comply with the International Conference on Harmonization (ICH) Good Clinical Practice guidelines in the conduct of their monitoring. Patients and other subjects whose records are reviewed have signed HIPAA-compliant authorizations granting access to the monitors. None of the suggested methods would allow the monitors to gain full access to VA systems or to see the records of patients who have not authorized access. As you know, this issue and its importance was discussed during a recent meeting with the Secretary.

2. VA medical centers throughout the country collaborate on clinical trials with pharmaceutical and medical device companies. VA also sponsors several large-scale clinical trials through its Cooperative Studies Program. The trials benefit veterans by giving them access to novel and cutting edge drugs, therapies or devices. They benefit VA by providing teaching and training opportunities, funds for equipment and other research needs, and by helping to attract high-quality researchers and clinicians to the VA health care system. The frequency and requirements of the monitoring are set in the protocol for the particular study. Monitoring occurs on varying periodic schedules (e.g., quarterly, semi-annually) for several hours to several days each time and sometimes occur on short notice. Because VA has not issued national guidance about data security requirements for clinical trial monitors, the data security requirements imposed vary throughout VA. This lack of consistency is troubling to sponsors engaged in studies at more than one VA facility. Study sponsors (including VA) have faced significant challenges in fulfilling their regulatory responsibilities. Some industry sponsors have objected to the background checks and fingerprinting that has been required in some areas and we know of two studies that have been cancelled in progress due to this issue. To ensure that veterans will continue to have the opportunity to participate in studies that may benefit them, it is crucial that VA identify a method that adequately protects the data while allowing monitors appropriate access.

3. Several medical centers have used methods for permitting monitor access that VHA believes substantially reduces the risks of unauthorized access to data and breach of patient confidentially. Attachment A describes these and other suggested methods that reduce risks to the VA's data systems, protect the privacy of veterans who have not

signed authorizations permitting access, and would be acceptable to monitors and sponsors. We have conferred with General Counsel who advises that these methods would meet both the requirements of the Good Clinical Practice guidelines and Food Drug Administration regulations.

4. Because full access to the medical records system is not required or being sought, and the patient has authorized the access that will be provided, we suggest the approval of the methods described in Attachment A as alternatives to additional security measures such as background checks or fingerprinting. VHA medical centers could then choose the method that best suits their facilities or particular clinical studies. Of course, when full access to VA data systems is required, background investigations and training will be necessary. To the extent that the Attachment A alternatives would deviate from any existing security requirements for such access, your approval will be deemed the grant of a waiver from such requirements.

5. In addition to using one of the suggested access methods, the following steps can reduce the risk to VA records and systems even further:

- Each research sponsor will warrant that its monitors understand the confidential nature of the VA information and protect its security.
- The signed HIPAA Authorizations for the patients whose records are to be monitored will be produced and reviewed by VA prior to it allowing access to those records. VA will deny access if a signed Authorization cannot be produced.
- Fully-encrypted VA computers will be used for the stand-alone download method.
- The computers used will be sanitized at the end of the monitoring visit and a Certificate of Sanitization will be issued and stored in the study records.
- Detailed procedures for the process of downloading appropriate information, and for the VA Driver method and the Limited Read-Only Access methods will be developed and disseminated by VHA to its research facilities to ensure full understanding and consistent implementation of the nationwide policy.
- VHA will request that the same or similar guidance be provided by the Office of Information and Technology to the local Information Security Officers and IT Staff at the VHA facilities to ensure that the procedures are applied consistently across VHA facilities.

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6. VHA suggests that appropriate staff from VHA and the VA Office of Information and Technology (OI&T) work together to develop detailed guidance to implement the acceptable options once approval is obtained. We ask that you concur with this plan to provide clear guidance about acceptable alternatives that researchers can use to ensure that our veteran-patients can continue to participate in clinical trials.

Michael J. Kussman, M.D.
Michael J. Kussman, MD, MS, MACP

Attachments

_____ _____
Robert T. Howard Date

_____ Approve _____Disapprove _____ Additional Information Required

Attachment A

Methods to Ensure Data Security When Clinical Trial Monitors Access Patient Data

1. Limited Read-Only Access to Selected Data –

A clinical patient group involving only study subjects who have consented to participate in the clinical trial can be established within CPRS. Permissions can be set to allow only authorized individuals (including clinical trial monitors) to have read-only access to records for this group. For multi-site clinical trials involving a VA principal investigator (e.g., VA, NIH, or industry sponsored study), read-only access of a clinical patient group may enable central monitoring that provides greater consistency in this effort. This option would likely represent the least resource intensive option for VHA.

2. VA Employee Driver –

This method is somewhat more resource intensive for VHA, but has been successfully employed by VA Medical Centers in oversight visits of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). A 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.

3. Stand-alone download –

Before any visit, the monitors would provide the VAMC with a list of particular data they desire to review on that visit. The VAMC would download that data, in advance, to a computer not connected to any VA system. The study monitor would be provided with access to that computer at the VAMC. The computer would be cleansed of the data after the monitoring visit. If a laptop is used to download these data, the laptop must be encrypted. Usually, this method would require a document signed by the VA employee who downloaded the data certifying that the data on the stand-alone computer were taken from and matches the data in the relevant VA system.

- In a variation, which would not require the monitor to provide a list of desired information in advance, the monitor would be given access to a stand-alone computer to which all study data have been downloaded. A VA certification to verify that the data are true would still be required. If a laptop is used to download these data, the laptop must be encrypted.

- In a further streamlined variation on this method, the VA facility would purchase a laptop computer to be dedicated to this purpose. The monitor would be present and witness the downloading of the requested data to the laptop computer to which the monitor would then be given access. No VA certification would be necessary and the laptop would be cleansed of the data after the monitoring visit.

Department of Veterans Affairs

Memorandum

Date: JUN 26 2008

From: Assistant Secretary for Information and Technology (005)

Subj: Clinical Trial Monitor Access (WebCIMS 397373)

To: Under Secretary for Health (10)

1. This is in response to your memorandum dated April 24, 2008. The Office of Information and Technology (OI&T) approves the Veterans Health Administrations (VHA's) request to use alternative methods of providing clinical trial monitors with access to pertinent medical records of Department of Veterans Affairs (VA) study subjects, with the following comments:

a. Paragraph 1: The data in question is currently being extracted by VHA's Office of Information, Data Warehousing Office. We recommend that VHA contact Mr. Jack Bates for comparisons and clarification which may prevent additional extractions and performance threats.
b. Paragraph 4: It is recommended that a consistent background check and sufficient training be a requirement of all clinical trial monitors.
c. Paragraph 5, first bullet: It is recommended that a checklist and accountability procedures are implemented within the audit process.
d. Paragraph 5, fourth bullet: The level of sanitation conducted at the end of the monitoring visit should be clearly defined.
e. Attachment A, #2, VA Employee Driver: It is recommended that users sign Rules of Behavior (ROB) and mandated to complete VA Security Awareness training.
f. Attachment A, #3, Stand-alone download, first paragraph: For access to the monitors, individual accounts will need to be established for users.
g. Attachment A, #3, Stand-alone download, second bullet: For access to the monitors, individual accounts will need to be established.

2. I agree that the we should work together to develop detailed guidance to implement acceptable options, and concur with the plan to provide clear guidance and acceptable alternatives that researchers can use to ensure that veteran-patients can continue to participate in clinical trials.

Robert T. Howard

Attachment:

Memo 4/24/08

*U.S. GPO: 1991-282-804-27336