From: OC GCP Questions
To: [redacted]
Subject: Monitor access to electronic medical records
Date: Monday, May 01, 2017 10:03:00 AM
Attachments: [redacted]

Good morning --

Many institutions and sites are going to a fully electronic record system. Your eTMF and/or EMR are your source records whether or not you use paper copies in the study files. If you do make certified copies of the medical records of study subjects, monitors and auditors will want to at least spot check the completeness of these records at the source - the electronic database or the EMR. How they view them is at your discretion however. Either looking over the shoulder of a study staff member or having limited access to the medical records is common.

The reason at least a spot check is necessary is that the records can be selectively copied. So even though they are certified copies they may not be complete records. The monitor/auditor is checking to ensure that study inclusion/exclusion are met and that there are no concomitant issues that would preclude the individual's participation in the study or confound the results.

In general, during an inspection FDA usually reviews original (source) records or certified copies of clinical trial records. For example, during an inspection of a clinical investigator (CI), the FDA investigator will evaluate the CI's practices and procedures to determine compliance with applicable regulations. Quite often CIs maintain copies of certain records in their study files, e.g., records from a hospital or other institution that must maintain the originals. FDA refers to these as shadow files. While it is acceptable to keep shadow files in the study records, should FDA conduct a bioresearch monitoring (BIMO) inspection of the study in question, the FDA investigator will expect to review at least a portion of the original source documents for such shadow files to verify their authenticity, even if the copies in the shadow files are certified as authentic copies. During the FDA inspection, the eTMF may be inspected for part 11 compliance

You may also want to look at FDA's Compliance Program Guidance Manual (CPGM) for the FDA inspection of clinical investigators during a bioresearch monitoring (BIMO) inspection of a clinical study site, available at: www.fda.gov/ICECI/EnforcementActions/BioresearchMonitoring/ucm133562.htm . In particular, you may want to review Part III, Inspectional, which identifies some of the things an FDA investigator will look for during a clinical investigator site inspection.

FDA would expect the monitor to have access to the EMR to verify data.

You may want to review FDA's guidance document on monitoring (link below)

https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM269919.pdf

Reporting Complaints Related to FDA–Regulated Clinical Trials –

Complaints related to FDA-regulated clinical trials should be reported to the office handling the type of study involved:

Biologics studies (including gene therapy and vaccine studies):
Call 301-827-6221
Fax 301-827-6748
(Division of Communication and Consumer Affairs, CBER)

Drug studies:
Call 301-796-3150
Fax 301-847-8748
(Division of Scientific Investigations, Office of Compliance, CDER)

Medical Device studies:
Call 301-796-5490
Fax 301-847-8136
(Division of Bioresearch Monitoring, Office of Compliance, CDRH)

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Sunday, April 30, 2017 2:21 PM
To: OC GCP Questions
Subject: Monitor access to electronic medical records

To Whom It May Concern,

A medical device company has asked me to take over monitoring responsibility for a site. In preparing for a monitor visit, the site has indicated that they will not allow me direct access to their electronic medical record (EMR) system nor will they permit "over the shoulder" view of the EMR system. I have further informed then that the protocol indicates "The investigator is responsible for ensuring the clinical monitor has access to all necessary records to ensure the intergrity of the date" however, they still refuse. I have informed the Sponsor of the situation and, so far, they have not taken any action. With that, can you please provide the current FDA position on monitor access to a study site's electronic medical records including corrective action(s).

Thank you.

[redacted]