From: OC GCP Questions
To: [redacted]
Subject: FDA stance on EMR and certified copies
Date: Tuesday, December 09, 2014 11:53:05 AM

Good morning --

In the past, our IT specialists have stated that FDA technically does not endorse any specific scenario for allowing monitors and auditors to review EMR data on study subjects. The method of having study staff bring up the records for viewing and printing those requested is, however, what we instruct our FDA investigators to do on inspections. This statement is related only to subjects in an FDA-regulated study.

That said, based on the limited information provided in your email, it appears the EMR could be your source documentation and since the CRA/auditor/inspector may not have access to the EMR, it appears certified copies would be required.

The term "Certified Copy" is defined in FDA's Final Guidance Computerized Systems Used in Clinical Investigations as: "A certified copy is a copy of original information that has been verified, as indicated by a dated signature, as an exact copy having all of the same attributes and information as the original." See: http://www.fda.gov/OHRMS/DOCKETS/98fr/04d-0440-gdl0002.pdf

If it is decided to have a certified copy substitute for the original, it would be desirable to have a "standard operating procedure" (SOP) describing how such copies would be made, verified, and documented. The person who certifies the copy as an accurate and complete representation of the original, having all of the same attributes and information should be the same person who actually made the copy from the original. Certification should be accomplished by having the person who makes the copy, sign or initial and date the copy to indicate it meets the requirements of a certified copy as described above. This should be described in the SOP and can be accomplished by initialing and dating each copy or by initialing and dating a document certifying copies in bulk. Whichever method is used the SOP should describe the procedure. (There are many ways to accomplish this, and the procedures described above are only suggested examples.)

As stated previous, 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 authenticity.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

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

From: [redacted]

Sent: Monday, December 08, 2014 12:24 PM
To: OC GCP Questions
Subject: FDA stance on EMR and certified copies

Dear GCP Officer,

I am an independent clinical researcher working with Sponsors and CROs to manage trials. I am coming across more and more centers who have an EMR and do not allow the monitors to have access to it (HIPAA or concerns about changing data in the records) – and so they provide certified print outs.

Is this acceptable to the FDA for clinical trial data? There are so many schools of thought that I really wanted input direct from the FDA. The concern being an FDA auditor were to go to such a site and demand access there may be more information that had not been reported. In that case my inclination would be the site would get the 483 not the CRO or Sponsor as we would have monitored the data we are provided in certified copies.

Please provide your guidance.

Regards,

[redacted]