From: OC GCP Questions
To: [redacted]
Subject: GCP question for source data
Date: Monday, March 31, 2014 12:40:22 PM

Good afternoon --

Based on the limited information provided in your email, it appears the EMR is your source documentation and since the CRA/auditor/inspector do 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.pd f

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.)

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.

A few guidance document links that might be helpful to you are listed below.

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM328691.pdf

http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126953.pdf

I hope this information is helpful. Please contact us 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

-----Original Message-----
From: [Redacted]
Sent: Monday, March 31, 2014 6:48 AM
To: OC GCP Questions
Subject: GCP question for source data

Hi sir,

Hope this email finds you well.
As one site used the EMR to record all subjects' medical information and it only granted the access to investigators (including PI and sub-investigator), no access to study nurse, CRA, auditor and inspector. Hence, the investigator decided to summarise all information including subjects' medical histroy, AE/SAE information, concomitant medication from EMR and write dowan on the paper as the source data. Is it acceptable? Or since the EMR was not accessible for CRA/auditor/inspector, is it required to print out all EMR information and ceritified by investigator as the certified copies of source doucments for SDV purpose? Please kindly advise.

Many thanks and regards,
[Redacted]