From: OC GCP Questions
Sent: Friday, January 16, 2015 11:31 AM
To: [redacted]
Subject: Question about Certified Copy of Original Information

Good morning ---

FDA regulations require very few signatures. As the guidance that you reference points out, we ask that the clinical investigator (PI) supervise and oversee the study but FDA does not specifically spell out how to do this. This is why internal SOPs are important. The protocol or internal procedures and delegation logs/task should outline who can sign off on study documents.

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.)

Please see:
Part 11, Electronic Records; Electronic Signatures — Scope and Application
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm072322.pdf

For general information on the use of computer systems in clinical trials in FDA regulated clinical trials, please reference the following guidance:

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070266.pdf

Electronic Source Data in Clinical Investigations:

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

I hope this information is helpful. Please contact us again at gcp.quesstions@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

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: [redacted]
Sent: Thursday, January 15, 2015 11:42 AM
To: OC GCP Questions
Subject: Question about Certified Copy of Original Information

To Whom it May Concern,

I am looking for some clarification on what the requirements are for certified copies of original source documentation from an EMR. I saw the definition of Certified Copy in the Guidance for Industry Computerized Systems Used in Clinical Investigations…

Certified Copy: 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.

Can the study coordinator that is printing the information be the one that verifies that the information is original? Does 'as indicated by a dated signature' mean that it was signed and dated by the person verifying or is it the electronic signature and date stamp on the printed copy? If a signature and date are required Could the study coordinator be the one to sign and date or would it need to be someone else?

Thank you for your time.

Regards,
[redacted]