From: OC GCP Questions
To: [redacted]
Subject: Source notes and GCP guidelines
Date: Wednesday, February 04, 2015 12:54:36 PM

Good morning ---

Please see my answers to your questions below. That said, FDA does not inspect electronic medical records (EMRs) for Part 11 compliance. The main point about EMRs is that they are developed and maintained by the "institution" for general patient medical records. As such, they are a part of the practice of medicine and FDA does not regulate the practice of medicine. It appears you are referring to certified copies.

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

We are frequently asked if sites may archive records by converting paper documents into an electronic format--in essence, creating certified copies of source documents. Neither FDA's regulations nor the ICH E-6 Good Clinical Practice: Consolidated Guidance http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf defines "certified copy", however, the term is mentioned in the E6 definitions for "source data" and "source document":

"1.51 Source Data: All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies)."

"1.52 Source Documents: Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories, and at medico-technical departments involved in the clinical trial)."

Although the term "certified copy" is not defined in the ICH E6 guidance, we attempted to define this term in the CCT Guidance referenced above:
"Certified Copy means a copy of original information that has been verified, as indicated by dated signature, as an exact copy having all of the same attributes and information as the original."

The use of certified copies as described above generally applies to situations where original records are copied to a different media for archiving purposes and the originals are destroyed. However, 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

Electronic Source Data in Clinical Investigations:
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM328691.pdf

A Risk-Based Approach to Monitoring:
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM269919.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

From: [redacted]
Sent: Tuesday, February 03, 2015 2:59 AM
To: OC GCP Questions
Subject: Source notes and GCP guidelines

Hi,

I would like to have your opinion or advice regarding the ***process reported below*** and especially the 2 last sentences. We have frequent issues with Electronic Medical Record that cannot be used because not validated or non accessible for sponsor. So site staff is printing all medical records and we used print-out for data monitoring.
1- in such case, we have to consider the print-out as source documents, right ? Correct
2- the signature of investigator is enough for certifying these documents or not ? Correct
3- if so, monitor from sponsor could not be allowed to add initials or date on this form as they are not "employed" by site and not on the Delegation Duties Form signed by PI ? Correct
4- as sponsor, we need to document which information were also available during the monitoring visit but how to document it correctly in such situation? See guidance document about concerning monitoring

Many thanks for your support on this matter,

My best regards

[redacted]