**From:** OC GCP Questions
**To:** [redacted]
**Subject:** Electronic Medical Records Source & Certified Copies
**Date:** Friday, February 13, 2015 10:11:14 AM

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Good morning –

The information in your email appears accurate. However a certified copy is not necessary when copies of EMR are produced. The use of certified copies generally applies to situations where original records are copied to a different media for archiving purposes and the originals are destroyed. In the scenario you describe, it sounds like certified copies of the hospital charts (EMRs) would not be necessary are the originals would generally be accessible if needed should a FDA inspection occur.

Your EMR is your source record. If certified copies are made 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. How they view them is at your discretion however. Either looking over the shoulder of a study staff member or having limited access is common. This would be the idea situation.

The reason at least a spot check is necessary is that the records can be selectively copied. So even though they are certified copies or copies of EMR 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.

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



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**From:** [redacted]
**Sent:** Wednesday, February 11, 2015 11:36 AM
**To:** OC GCP Questions
**Subject:** Electronic Medical Records Source & Certified Copies

Dear Sir or Madam:

Please kindly advise if a clinical investigator would be required to document on each individual record printed from an Electronic Medical Record that it is a certified copy.

In this case the clinical investigator has generated an over arching note-to-file that states the following: "*This note-to-file is to document that all copies printed from electronic records in subject's source files represents a complete and accurate representation of all the information recorded in Allscripts. Additional EMR records will be printed and filed when subjects are seen on an ongoing basis during their participation in the study".* This note to file is signed and dated by the clinical investigator.

All records in this clinical investigators EMR include the date of the entry and the investigator's electronic signature. Any changes to the electronic medical record can be tracked via audit trail.

Please advise if this note-to file is adequate documentation to certify that all printed records from the Electronic Medical Record are accurate and verifiable? Relevant FDA Guidance has been reviewed and we feel we are in compliance.

*Electronic Source Data in Clinical Investigations (September 2013)*
*III. Electronic Source Data*
*Electronic source data are initially recorded in electronic format. They can include information in original records and certified copies of original records of clinical findings, observations, or other activities captured prior to or during a clinical investigation used for reconstructing and evaluating the investigation.*
*IV. Use and Description of Computerized Systems in Clinical Investigations*
*… FDA does not intend to assess the compliance of EHR's with part 11*

*Relevant FDA Guidance*
*Computerized Systems Used in Clinical Investigations (May 2007)*
*C. Source Documentation and Retention*
*When original observations are entered directly into a computerized system, the electronic record is the source document.*

Your advise would be greatly appreciated.

Thank you.

[redacted]