From: OC GCP Questions
To: [redacted]
Subject: Study documentation
Date: Friday, March 13, 2015 11:27:46 AM

Good morning –

Many institutions and sites are going to a fully electronic record system. Your EMR can be your source record. If you do make certified copies 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 to the medical records is common.

The reason at least a spot check is necessary is that the records can be selectively copied. 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.

You may also want to look at FDA's Compliance Program Guidance Manual (CPGM) for the FDA inspection of clinical investigators during a bioresearch monitoring (BIMO) inspection of a clinical study site, available at: http://www.fda.gov/ICECI/EnforcementActions/BioresearchMonitoring/ucm133562.htm In particular, you may want to review Part III, Inspectional, which identifies some of the things an FDA investigator will look for during a clinical investigator site inspection.

ICH E-6 Good Clinical Practice: Consolidated Guidance
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf
Please see this guidance for 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)."

The guidances listed below might be helpful to you.

Part 11 –Electronic Records --
http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126953.pdf

Computerized Systems Used in Clinical Investigations –
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070266.pdf

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov for 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: Thursday, March 12, 2015 4:07 PM
To: OC GCP Questions
Subject: Study documentation

Dear Office Of Good Clinical Practice:

I have a question surrounding the interpretation of the September 2013 Guidance for Industry Electronic Source Data in Clinical Investigations with respect to research records maintained by a sponsor investigator. It has been our interpretation that the following statement implies that the records are to be maintained / kept by the clinical investigator.

> *c. Transcription of Data From Paper or Electronic Sources to the eCRF*
>
> *Data elements can be transcribed into the eCRF from paper or electronic source documents. The authorized person transcribing the data from the source documents is regarded as the data originator. For these data elements, the electronic or paper documents from which the data elements are transcribed are the source. These data must be maintained by the clinical investigator(s) and available to an FDA inspector if requested (e.g., an original or certified copy of a laboratory report, instrument printout, progress notes of the physician, the study subject's hospital chart(s), nurses' notes).*[9]

That being said, it has been our long standing practice to have investigators print relevant electronic medical records and maintain a certified/signed copy of these records to validate that they are the accurate source documents for the clinical trial. As we move increasingly to a completely electronic world, we are beginning to get push back from some investigators as they do not want to print the electronic health records but maintain them in the hospital medical record system.

Could you provide input regarding FDA's expectation as to how source documents should be kept at the research site? Thank you in advance for your response.

Best regards,

[redacted]