From: OC GCP Questions
Sent: Tuesday, July 01, 2014 10:45 AM
To:
Subject: Regarding electronic records in research

Good morning –

Many institutions and sites are going to a fully electronic record system. It appears that the situation you describe may not conflict with FDA regulatory requirements

While I can't comment on your recent FDA inspection, your EMR is your source record whether or not you use paper copies in the study files. 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. So even though they are certified copies 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.

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.

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

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.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

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: Monday, June 30, 2014 2:25 PM
To: OC GCP Questions
Subject: Regarding electronic records in research

Ms. Foltz:

After review of the Federal Regulations and Guidance for Industry regarding electronic signatures, we have initiated a less-paper regulatory records system, whereby “wet signature” documents are kept in paper form and all other documents are captured electronically.

Recently we experienced an FDA audit and were asked to print document and recreate the regulatory binder for the study under review.   This was not difficult because the study was opened less than a year ago.

As we consider how to best be FDA audit ready at all times, we wonder whether you can give us some additional guidance around our system. If, for instance, a study has been ongoing for several years, it would be a large undertaking to print all the information and prepare a regulatory binder for FDA review. As we understand it, the only other way for the FDA to audit the records would be to provide an employee to sit with the auditor and bring up records and print as they are requested.

We will welcome your thoughts. Thank you for your assistance.
ώǈŜŘl·ŐűŜŘϐ

-