From: OC GCP Questions
To: [redacted]
Subject: Record Retention for Clinical Trial Sites
Date: Thursday, November 06, 2014 1:45:55 PM

Good afternoon --

Quite often clinical investigators 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.

That said, under FDA regulations, it is not necessary to keep shadow files.

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 expectation is that investigators and sub-investigators and study staff will be knowledgeable about good clinical practice, including human subject protection, data integrity, recordkeeping, etc.

FDA's regulations on investigator recordkeeping and retention requirements for drug studies are located in the investigational new drug (IND) regulations at 21 CFR 312.62. (The IND regulations may be accessed at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRsearch.cfm?CFRPart=312.) Regarding record retention, the regulations state:

Record retention. An investigator shall retain records required to be maintained under this part for a period of 2 years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified.

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
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Office of Good Clinical Practice
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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, November 06, 2014 11:57 AM
To: OC GCP Questions
Subject: Record Retention for Clinical Trial Sites

Good Morning,

I have been trying to find reference in the regulations, but am having trouble, so I hope you can help. Our site stores regulatory documents separate from patient documents. Being fairly new, I am trying to find out if this is a regulation or if this is an unnecessary process?

Thanks for your help,

[redacted]