From: OC GCP Questions
To: [redacted]
Subject: Storage of Source Documents in Clinical Trails
Date: Monday, December 04, 2017 8:45:00 AM

Good morning --

There is no regulatory requirement that clinical trial records be kept in a fire-proof storage cabinet.

Under 21 CFR 312, sponsors and investigators are required to retain records and reports required by this part for 2 years after a marketing application is approved for the drug; or if an application is not approved for the drug, until 2 years after shipment and delivery of the drug for investigational use id discontinued and FDA has been notified. In the ICH E6 Guidance for Industry entitled Good Clinical Practice Consolidated Guidance (seehttps://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf), you will find suggestions in Section 8 for what "essential" documents should be retained by the sponsor and investigator. As noted in this guidance, essential documents are those documents that individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator, sponsor, and monitor with standards of GCP and will applicable regulatory requirements. Filing these documents in a timely manner can greatly assist in the successful management of a trial by the investigator, sponsor and monitor. These documents are the ones that are usually audited by the sponsor's independent audit function and inspected by the regulatory authorities) as part of the process to confirm the validity of the trail conduct and integrity of data collected.

Although it is important to preserve these documents, it is not necessary to keep them in a fire-proof cabinet.

Kind regards,

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Office of the Commissioner, FDA

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From: [redacted]
Sent: Friday, December 01, 2017 8:22 AM
To: OC GCP Questions <gcp.questions@fda.hhs.gov>
Subject: Storage of Source Documents in Clinical Trails

Good day. Is it required that sites store their source documents/regulatory documents in a fire proof cabinet?

[redacted]

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