**From:** OC GCP Questions
**To:** [redacted]
**Subject:** Inquiry: Are there GCP mandatory regulations on...
**Date:** Thursday, October 16, 2014 12:28:23 PM

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Good afternoon –

FDA regulations on storage of study documents are not that specific. In general, FDA expects that reasonable steps would be taken to maintain control of the study records, the privacy and confidentiality of study subjects, and the confidentiality, completeness and accuracy of study records.

Those responsible for clinical trial data (records) should have a full understanding of the issues, obligations, and requirements related to data management and ownership. The sponsor, or other owners of the data, should retain all of the sponsor-specific essential documents pertaining to the trial.

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, October 15, 2014 6:54 PM
**To:** OC GCP Questions
**Subject:** Inquiry: Are there GCP mandatory regulations on...

Dear GCP
Please help me with this inquiry. I searched everywhere on FDA.gov and no luck.
Any GCP/FDA references on "types of in-house paper only record storage for document retention"… as in, does the FDA GCP for drug development under an IND mandate that:
>Onsite storage cabinets be fire proof?
These are very heavy I heard, but I cannot find anything on FDA.gov to give us a type of cabinet… locking yes, or limited access to the room I understand, but the cabinet type?
>The records storage room have a sprinkler or sprinkler system? Does the sprinkler system need to be a powder-type extinguishing material?

>The records storage room have security access limited to others? This is a given to me, but I cannot find anything in writing.

Any information would be a tremendous help. We "may" be moving offices in 2015 and at the new location, I want to ensure how/what we store our hard copy essential documents, SOPs, etc. are

FDA-compliant. ICH E6 GCP did not state any information. Should I follow Part 11 guidelines even though it is not paper?

Best
[redacted]