From: OC GCP Questions
To: [redacted]
Subject: clarification needed
Date: Tuesday, January 17, 2017 1:12:00 PM
Attachments: [redacted]

Good afternoon --

No, there's no specific requirement in the regulations for locked cabinets to store clinical trial records. The only place in the IND regs that I'm aware of that mentions a locked cabinet is 21 CFR 312.69 (for storage of investigational drugs that are also subject to the Controlled Substances Act).

I also checked the ICH E-6 Good Clinical Practice: Consolidated Guideline, but again, there is no recommendation about use of locked cabinets for keeping trial records in locked cabinets.

FDA's regulations relating to the confidentiality of clinical trial subjects includes the IRB regulations at 21 CFR 56.111, which outlines the criteria for IRB approval of research. One of those criteria [21 CFR 56.111(a)(7)] requires that, where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. Note that neither the regulations or even guidance do not specifically address the methods used to maintain the confidentiality of records identifying the subject nor do they prohibit sponsors/CROs from receiving subject information, even with identifiers. Typically, study sponsors, CROs, and sites usually follow their own Standard Operating Procedures (SOPs) that direct document handling and maintaining confidentiality

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

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Office of Good Clinical Practice
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From: [redacted]
Sent: Saturday, January 14, 2017 3:16 PM
To: OC GCP Questions
Subject: clarification needed

The organization that I am working with is expanding to work in the office of a private practice physician. We have limited storage space. My question is: is it required that all study related documents to include case report forms (paper) and subject source documents be kept in a locked secure space?

As opposed to being kept on a book shelf in an unlock exam room?

Thank you for your assistance.

[redacted]

[redacted].