From: OC GCP Questions
To: [redacted]
Subject: Good Clinical Practice Question
Date: Thursday, October 01, 2015 6:48:02 AM

Good morning –

FDA regulations are silent as to how study records should be stored. Therefore sites and institutions should develop their own standard operating procedures (SOPs) regarding this issue. You state you have SOPs in place.

The general expectation is that there should be adequate provisions in place to protect the privacy of subjects and to maintain the confidentiality of data. As stated the regulations or even guidance specifically address the methods used to maintain the 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: Wednesday, September 30, 2015 3:35 PM
To: OC GCP Questions
Subject: Good Clinical Practice Question

Good afternoon,

Is there requirement either at CFR or GCP level as to how study records are stored? For example, in locked filing cabinets, password protected computers, etc. We do have this in our SOPs but wanted to back it up with a regulation or a GCP. I've been searching and could not find anything.

Thank you so much for any assistance you can provide.

[redacted]