

From: OC GCP Questions
To: [REDACTED]
Subject: Shared storage area
Date: Monday, January 30, 2017 9:48:00 AM
Attachments: [REDACTED]

Good morning –

FDA's regulations and guidance are not specific regarding the requirements for the storage area for study records. Sponsors may have specific requirements and you should also consider your ability to maintain the confidentiality of records identifying study subjects and the integrity of the records.

Kind regards,

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Office of Good Clinical Practice
Office of the Commissioner, FDA



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: Saturday, January 28, 2017 2:22 PM
To: OC GCP Questions
Subject: Shared storage area

Dear Sir/Madam,

I have one storage area limited access, can the clinical data management team and the clinical monitoring team share same storage area for each department documentations?

Thanks a lot in advance for your support,

Regards,

[REDACTED]
[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]