From: OC GCP Questions
To: [redacted].
Subject: Clinical trials compliance and space challenges
Date: Thursday, June 15, 2017 1:47:00 PM
Attachments: [redacted]

Good afternoon –

FDA's regulations do not specifically address your question, so there is nothing that would prohibit sharing office space. You would need to be able to ensure compliance with the regulatory requirements. It would be important to keep documents separate. As for the investigational product, you would need to keep these separate and also control access to them. Another consideration would be the confidentiality of subjects when sharing space. The mere presence of a co-worker does not definitively equate to a breech in subject confidentiality. The medical practice administrators are in the best position to review the medical practice's policies and procedures, the controlling laws and the specifics of this situation to determine if the subjects' rights are at risk.

Also sharing equipment is not addressed in FDA regulations. I suggest you consult with your institutional officials and develop procedures that are in line with your institutional policies.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Thursday, June 15, 2017 12:05 PM
To: OC GCP Questions
Subject: FW: Clinical trials compliance and space challenges

Dear FDA,

Please see my questions below. Can we set-up an institutional CDA that covers our employees in this area as a group to documents in this shared space? Do they have such documents at other academic medical institutions?

Please call me if easier to discuss by phone.

Thank you,

[redacted]

[redacted]

[redacted]

From: [redacted]
Sent: Thursday, June 15, 2017 9:03 AM
To: [redacted]
Subject: Clinical trials compliance and space challenges

Hi everyone,

Space Question:

Can someone offer or cite the regulations related to having study coordinators who work on different clinical trials who are employed across different Divisions (e.g., Pulmonary, Rheumatology, Endocrine) sharing the same contiguous space. For example, is it permissible to have a large, open room with 40 cubicle workstations shared among various study teams in an open layout?.

1. Can you have a workstation layout with study coords working on different trials sitting side by side?

2. With regard to copiers that print study-related material and study subject information….are there restrictions on how that copier must be protected? Specifically, can the copier be shared across study teams or does each study team need an independent copier that is only accessible to that study team assigned to that specific study?

Or, if you know who I should contact at the FDA to ask these questions?

Thank you,

[redacted]