From: OC GCP Questions
To: [redacted]
Subject: Monitor area for record review
Date: Monday, December 07, 2015 6:19:35 AM

Good morning –

There should be adequate provisions in place 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 from receiving subject information. Typically, study sponsors, CROs, and sites usually follow their own Standard Operating Procedures (SOPs) that direct document handling and maintaining confidentiality.

Additionally in the US there is HIPPA (privacy) requirement for medical records. Unfortunately, I cannot advise you regarding matters concerning the Health Insurance Portability and Accountability Act (HIPAA) as HIPAA and its related statutes are under the jurisdiction of the Office for Civil Rights (OCR) and not FDA. You may wish to consult the Health Insurance Portability and Accountability Act (HIPPA) For questions regarding issues pertaining to HIPAA, you may contact OCR directly at OCRPrivacy@hhs.gov. Here also is a link to OCR's general website for HIPAA http://www.hhs.gov/ocr/privacy/, and OCR also has HIPAA Frequently Asked Questions that can be accessed at http://www.hhs.gov/ocr/privacy/hipaa/faq/index.html.

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

From: [redacted]
Sent: Friday, December 04, 2015 12:41 PM
To: OC GCP Questions
Subject: Monitor area for record review

To Whom It May Concern:

An investigative site that I monitor at recently changed the space provided for monitoring to an open reception area immediately adjacent to the entrance of the clinic office. This area is directly passed by the 30+ office workers constantly coming in & out of the office not to mention delivery people, and patients asking for directions; site personnel also congregate in the area holding personal and business conversations. While I'm not aware of any regulations related to conditions required by sites for reviewers, I was wondering if the open space constituted a violation of HIPAA since passersby could easily look at the computer

screen or the hard copy records being reviewed by the monitor. I have advised the Sponsor of my concern but, there does not appear to be any change in the situation as described. Please advise of any action I could take other than to decline further work at this location.

[redacted]