From: OC GCP Questions
To: [redacted]
Subject: Question on EMR access
Date: Friday, January 24, 2014 11:19:39 AM

Good morning --

I cannot comment on whether a monitor can review patients EMRs (patients not considered subjects in a FDA-regulated clinical trial). You question crosses over in the privacy rules under HIPPA. 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. For questions regarding issues pertaining to privacy and confidentiality of medical records, you may wish to contact OCR directly at OCRPrivacy@hhs.gov. I suggest you send your question to OCR to get their response. 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. You may also want to discuss your question with your institution's Privacy Officer

In the past, our IT specialists state that FDA technically does not endorse any specific scenario for allowing monitors and auditors to review EMR data on study subjects. The method of having study staff bring up the records for viewing and printing those requested is, however, what we instruct our FDA investigators to do on inspections. This statement is related only to subjects in an FDA-regulated study.

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

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.

-----Original Message-----
From: [Redacted]
Sent: Thursday, January 23, 2014 5:38 PM
To: OC GCP Questions
Subject: Question on EMR access

Can a monitor review electronic medical records if a site provides complete electronic medical record access to all patients seen at an institution or facility instead of limited access to their system for only the subjects who have signed an informed consent to participate in a study?

Thanks,

[Redacted]