From: OC GCP Questions
To: [redacted]
Subject: Clinical Study Monitors Present during FDA Inspection
Date: Monday, June 02, 2014 1:55:22 PM

Good afternoon –

Study site monitors are generally not present during a FDA inspection.

I can point you to some very helpful links on FDA website.

FDA uses Compliance Program Guidance Manuals (CPGM) to direct its field personnel on the conduct of inspectional and investigational activities. They are located on the following web page:
http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm160670.htm

Please see the guidance document below on monitoring. Occasionally sponsors and or CROs are present during the real time inspection as they can offer some added guidance and information.
http://www.fda.gov/downloads/Drugs/.../Guidances/UCM269919.pd

Additionally, please see the guidance document that explains FDA clinical investigator inspections. (See link below)
http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126553.pdf

Please see the links below to FDA's Good Clinical Practice website. You will find useful information at this site that includes guidances, regulations, and other FDA relevant information.
Clinical Trials

FDA Basics > What does FDA inspect?

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, May 30, 2014 2:10 PM
To: OC GCP Questions
Subject: Clinical Study Monitors Present during FDA Inspection

Hello,

I am wondering if you could answer the following, as I have been unable to find information on such:

Are Clinical Study Monitors permitted to be on-site during an FDA Audit of a Clinical Investigation which is monitored by the Mnnitor?

Kind Regards,
[redacted]