From: OC GCP Questions
To: [redacted]
Subject: additional IRB responsibilities when FDA observes study procedures
Date: Wednesday, February 04, 2015 11:05:11 AM

Good afternoon –

Generally the reviewing IRB is not involved in an FDA inspection at an investigative site. You may review FDA compliance programs for sponsors, clinical investigators, and IRBs at the link below.

Clinical Trials and Human Subject Protection > Bioresearch Monitoring Program (BIMO)

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: Monday, February 02, 2015 3:40 PM
To: OC GCP Questions
Subject: additional IRB responsibilities when FDA observes study procedures

Good afternoon,

What, if any, additional responsibilities does the IRB have when an investigative site under its review has been informed that an FDA representative will be on site to observe study procedures (i.e. blood draws)?

Thank you,
[redacted]