

**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](mailto: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.

---

**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]