From: OC GCP Questions
To: [redacted]
Subject: Question about IRB Audits
Date: Monday, July 28, 2014 10:32:15 AM

Good morning —

FDA regulations do not specifically address your question therefore sponsors, institutions and others may develop their own standard operating procedures (SOPs) to address specific situations or issues. Companies are free to set-up their own internal infrastructures to ensure the integrity of a clinical trial (IRB internal audits).

FDA uses Compliance Program Guidance Manuals (CPGM) to direct its field personnel on the conduct of inspectional and investigational activities. The CPGM's described below form the basis of FDA's Bioresearch Monitoring Program. The purpose of each program is to ensure the protection of research subjects and the integrity of data submitted to the agency in support of a marketing application. The link below describes the IRB CPGM.

http://www.fda.gov/downloads/ICECI/EnforcementActions/BioresearchMonitoring/UCM133768.pdf

Please also see the guidance document on a risk-based approach to monitoring.

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM269919.pdf

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, July 25, 2014 6:57 PM
To: OC GCP Questions
Subject: Question about IRB Audits

To whom it may concern,
There are arguments against and in favor of included IRB GCP Audits audits as part of the Sponsor Audit Plans for the US. As a consequence of this different opinions there are companies that are performing IRB audits and others not. As this is not a requirement in the regulations, do you think that it is recommendable and independence could be maintained?
Thanks in advance for you answer. Warm regards,
[illegible]