From: OC GCP Questions
To: [redacted]
Subject: Satellite Sites - SIV and Interim Monitoring Visit
Date: Friday, January 16, 2015 11:22:11 AM

Good morning –

Your question was forwarded to my office for a response. FDA regulations are not that specific when it comes to SIVs. Therefore sponsors can develop their own standard operating procedures for training and monitoring. The expectation is that investigators, sub-investigators, and study staff will be knowledgeable about good clinical practice, including human subject protection, data integrity, recordkeeping, etc. Note that sponsors have discretion in determining what qualifications will be needed to conduct a study and may identify in the protocol a required frequency of GCP training, in which case the investigator and sub-investigators would be expected to meet that frequency of training in order to comply with the sponsors requirements. Every effort should be made to train the investigational sites. Additionally monitoring of a clinical investigation should be frequent enough to ensure compliance with the protocol and FDA regulations.

Please see the link below to FDA guidance on Oversight of Clinical Investigations – 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: Wednesday, January 14, 2015 4:37 PM
To: CDER DRUG INFO
Subject: Satellite Sites - SIV and Interim Monitoring Visit

Dear FDA staff,

I would like to know what is the FDA expectation about having a site initiation visit (SIV) and interim monitoring visits in a research facility (satellite site) that will potentially conduct protocol patient's visits.
Is this required?
In some cases the CRA visits the main site only, in the SIV.
[redacted]