From: OC GCP Questions
To: [redacted]
Subject: Risk Based Remote Monitoring
Date: Thursday, June 08, 2017 6:56:00 AM
Attachments: [redacted]

Good morning --

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

Please see FDA's guidance document on a Risk Based Approach to Monitoring (above). It discusses documentation throughout the document.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Wednesday, June 07, 2017 6:55 PM
To: OC GCP Questions
Subject: Risk Based Remote Monitoring

Can you please provide the FDA expectations of appropriate documentation to be present in the site file where the Sponsor elects to conduct remote monitoring rather than a physical visit. I currently have a Sponsor who thinks the Site Visit Log should be documented when a remote monitor visit is done but I disagree because the site is not being visited by me and I feel making an entry on the Site Visit Log would be confusing if not misleading to a reviewer. Please advise how FDA would recommend a remote monitoring visit to be documented. Thank you.

[redacted]