From: OC GCP Questions
To: [redacted]
Subject: Sponsor oversight of CRO
Date: Friday, December 08, 2017 2:26:00 PM
Attachments: [redacted]

Good afternoon --

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. However, FDA would expect a sponsor who contracts to a CRO to review more than their SOPs. The is a GCP website so I cannot comment on QMS.

That said I can give you information on monitoring. Generally monitoring of clinical investigations is done by the sponsor or CRO. Please see the new monitoring draft guidance on risk base approach to monitoring. (link below)

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

It states --

For purposes of this guidance, monitoring generally refers to the methods used by sponsors of investigational studies, or CROs delegated responsibilities for the conduct of such studies, to oversee the conduct of and reporting of data from clinical investigations, including appropriate investigator supervision of study site staff and third party contractors. The primary focus should be on the processes that are critical to protecting human subjects, maintaining the integrity of study data, and compliance with applicable regulations. The findings should be used to correct investigator and site practices that could result in inadequate human subject protection and/or poor data quality.

On-site monitoring is an in-person evaluation carried out by sponsor personnel or representative(s) at the site(s) at which the clinical investigation is being conducted. On-site monitoring can identify data entry errors (e.g., discrepancies between source records and CRFs) and missing data in source records or CRFs; provide assurance that study documentation exists; assess the familiarity of the site's study staff with the protocol and required procedures; and assess compliance with the protocol and investigational product accountability.

If a sponsor of an IND study delegates the responsibility for ensuring proper monitoring to a CRO, FDA regulations (21 CFR 312.52) require the written transfer of any obligations from a sponsor to a CRO and require the CRO to comply with the regulations.37 Although sponsors can transfer responsibilities for monitoring to a CRO(s), they retain responsibility for oversight of the work completed by the CRO(s) who assume this responsibility.

Additionally, footnote 10 on page three of this guidance gives you a link to auditing a clinical trial.

We also have written Compliance Programs covering each of our inspection programs which serve as instructions to FDA field investigators and headquarter staff regarding how to conduct inspections. The compliance program covering CROs and Sponsors is found on the web at https://www.fda.gov/downloads/ICECI/EnforcementActions/BioresearchMonitoring/UCM133770.pdf If you refer to Part III you will find our procedures which would be followed for inspecting CROs.

Kind regards,

Doreen M. Kezer, MSN

Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Thursday, December 07, 2017 7:58 AM
To: OC GCP Questions <gcp.questions@fda.hhs.gov>
Subject: Sponsor oversight of CRO

Dear all,

We are currently in discussion at our CRO with three companies, who will possibly outsource clinical trials to us. Instead of performing an 'Vendor Audit' reviewing our QMS, they request access to our SOP system for review of the SOPs, templates and forms. This they will do from their offices.

We have had discussions (lengthy!) asking for a rationale for not performing a vendor audit, but instead only reading the SOPs. We, from our side, would like them to come to our office and perform an regular audit, which, in our opinion, will give them a full oversight of our QMS.

What is the FDA standpoint on the requirements for sponsor's oversight of CROs? We believe that it is far from enough to only review SOPs without having the full context of the QMS.

Med vänlig hälsning/Kind regards,

[redacted]

[redacted]