From: OC GCP Questions
To: [redacted]
Subject: sponsor oversight
Date: Wednesday, March 07, 2018 8:41:00 AM
Attachments: [redacted]

Good morning –

It may depend on the terms of the contractual agreement between the CRO and the sponsor, in which case it's a legal question that we cannot answer.

Under FDA regulations sponsor transfer of obligations to a CRO can be for full or partial responsibilities. Whatever the contract states is what FDA would inspect against.

CROs are mentioned in FDA regulations listed below.

CRO is defined in FDA regulation 21 CFR 312.3 -- it states --

Contract research organization means a person that assumes, as an independent contractor with the sponsor, one or more of the obligations of a sponsor, e.g., design of a protocol, selection or monitoring of investigations, evaluation of reports, and preparation of materials to be submitted to the Food and Drug Administration.

21 CFR 312.52 states --

Transfer of obligations to a contract research organization. (a) A sponsor may transfer responsibility for any or all of the obligations set forth in this part to a contract research organization. Any such transfer shall be described in writing. If not all obligations are transferred, the writing is required to describe each of the obligations being assumed by the contract research organization. If all obligations are transferred, a general statement that all obligations have been transferred is acceptable. Any obligation not covered by the written description shall be deemed not to have been transferred.

(b) A contract research organization that assumes any obligation of a sponsor shall comply with the specific regulations in this chapter applicable to this obligation and shall be subject to the same regulatory action as a sponsor for failure to comply with any obligation assumed under these regulations. Thus, all references to "sponsor" in this part apply to a contract research organization to the extent that it assumes one or more obligations of the sponsor.

What the transfer of obligations spelled out in 21 CFR 312.52 does is give the contracted party regulatory responsibilities for whatever they contract to do. This allows FDA to take regulatory action against the contracted party whenever inspectional findings at the contracted site evidence failure to comply with the pertinent regulations. That does not, however, completely relieve the sponsor of their regulatory responsibilities. FDA still holds the sponsor responsible for studies conducted under their auspices. Therefore, sponsors need to ensure that parties to whom they contract what the regulation delineate as their responsibilities comply with the regulations. While there are probably a number of ways to ensure this, the most common way is to audit the practices of the contracted party, both before issuing the contract and during the course of the study.

Kind regards,

Doreen M. Kezer, MSN
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From: [redacted]
Sent: Tuesday, March 06, 2018 3:27 PM
To: OC GCP Questions <gcp.questions@fda.hhs.gov>
Subject: sponsor oversight

Good afternoon,

I have a question regarding a sponsor's responsibility for oversight of a vendor's vendor. If the sponsor had a CRO that contracted with another vendor to perform a service for that sponsor's study, what is the sponsor's responsibility for oversight of that third party vendor?

Thank you.

[redacted]