From: OC GCP Questions
To: [redacted]
Subject: Requirement for Quality Agreement with CROs
Date: Thursday, March 08, 2018 8:08:00 AM
Attachments: [redacted]

Good morning –

Please see FDA regulation found at 21.CFR 312.52 – Transfer of obligations to a contract research organization – (Please note the regulations do not address "Quality Agreements" with CROs.)

(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.

The sponsor who hires a CRO determines the parameters for the work that CRO is to accomplish. Both the sponsor and the CRO therefore have a responsibility to understand what is required and to ensure that they are compliant with the regulations that pertain. A CRO cannot blame a sponsor if they are found to be noncompliant during a BIMO inspection. Both parties have the responsibility to comply with the pertinent regulations independent of each other.

Kind regards,

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This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: [redacted]
Sent: Thursday, March 08, 2018 7:36 AM
To: OC GCP Questions <gcp.questions@fda.hhs.gov>
Subject: Requirement for Quality Agreement with CROs

What is the Agency expectation on the need for Quality Agreements with CROs?
Quality agreements are discussed under GMP guidance documents however not for GCP.

Is the Transfer of Obligations document used in GCP acceptable if defines the specific roles roles and responsibilities transferred by Sponsor to the CRO, and includes text indicating that the CRO "..must meet all applicable laws and regulations ." Would the latter statement be considered too vague ?
Thank you in advance for your feedback.
[redacted]