From: OC GCP Questions
To: [redacted]
Subject: Clinical Operations Contracting Question
Date: Wednesday, April 19, 2017 8:54:00 AM
Attachments: [redacted]

Good morning –

Generally the investigator employees the coordinator but FDA regulations do not specifically address this question. When the regulations are silent, institutions are free to develop their own procedures and practices as long as applicable regulatory requirements are met. Also we cannot comment to contract questions. It might be helpful to contact your legal department. However we can offer the following information below.

FDA's regulation at 21 CFR 312.3(b) states: "In the event an investigation is conducted by a team of individuals, the investigator is the responsible leader of the team. `Subinvestigator' includes any other individual member of that team." 21 CFR 312.53(c)(1)(viii) requires the investigator to provide "A list of the names of the subinvestigators (e.g., research fellows, residents) who will be assisting the investigator in the conduct of the investigation(s)."

Most research coordinators is perform critical study functions and collect and evaluate study data, this coordinator should be listed in Block #6 on the 1572 form. However if the research coordinator is only transcribing data and maintaining study files, the coordinator does not need to be listed.

Kind regards,

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

From: [redacted]
Sent: Monday, April 17, 2017 2:52 PM
To: OC GCP Questions
Subject: Clinical Operations Contracting Question

Dear representative,

My questions relates to a pharma or biotech company providing study coordinator resources for an investigative site.

If a clinical trial site needs additional coordinator resources to adequately conduct a clinical trial what are the best options for the sponsor company to assist with this that best complies with GCP and doesn't present the appearance of conflict of interest?. I'd also like to consider

the option that is most expedient to get the resource to the site.

1. Sponsor contracts and pays directly for a third-party company to provide the needed coordinator resources for the site?

2. The clinical trial site contracts and pays directly for the needed coordinator resources? The sponsor would ultimately pay for the coordinator resource for the site through the Clinical Trial Agreement.

3. Would there be a difference in the option chosen if the coordinator would not be touching patient/subject information i.e. completing CRFs, etc.? If the coordinator resource was doing more prescreening activities, i.e. chart review, answering phones, setting up initial subject visits?

Thank you in advance for your response.

Best regards,