From: OC GCP Questions
To: [redacted]
Subject: RE: Transfer of Obligations
Date: Wednesday, February 19, 2014 11:22:00 AM

Good morning,

The definition of a CRO is outlined in 21 CFR 312.3 -- *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.

FDA's regulations allow a sponsor to transfer the responsibility for any or all of the obligations set forth in 21 CFR part 312 to a contract research organization as described in § 312.52, transfer of obligations to a contract research organization. If a sponsor contracts with a CRO to perform certain responsibilities but does not transfer these obligations as described in § 312.52, FDA will consider the sponsor fully responsible for these obligations and may initiate actions against the sponsor for failure of the CRO to comply with the regulatory requirements. It appears appropriate to include both the CRO and Clinical Coordinating Center on the 1571 of you as a sponsor are transferring obligations to both entities.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Patrick J. McNeilly, Ph.D., C.I.P.
Office of Good Clinical Practice
Food and Drug Administration

From: [REDACTED]
Sent: Tuesday, February 18, 2014 7:53 PM
To: OC GCP Questions
Subject: Transfer of Obligations

We are a [REDACTED] with an IND in place and a Phase 2 study beginning shortly. Our question concerns our transfer of obligations statements on the 1571. We are currently using both a major CRO to conduct the study and a Clinical Coordinating Center which separately okays patient acceptance into the study by reviewing the investigator's reports at screening of adherence to inclusion/exclusion criteria. I believe we need to include both the CRO and the CCC

on the transfer of obligations sections of the 1571. Your thoughts?

[REDACTED]