**From:** OC GCP Questions
**To:** [redacted]
**Subject:** Advice on Sponsor transfer of responsibilities to a phase I unit
**Date:** Saturday, September 20, 2014 10:44:15 AM

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Good morning —

The transfer of obligations to a contract research organization is located in FDA regulations under 313.52. (See below)
CFR - Code of Federal Regulations Title 21

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.

You would want to avoid the appearance of conflict of interest. I don't think you can do that if the CRO is also the investigator of the clinical trial. Additionally a CRO can supply a monitor for a study. As stated above, sponsors can contract out some or all of their responsibilities – such as development of the protocol, selection of the clinical investigators, monitoring of the study, review of adverse events (commonly the purview of a medical monitor), data management, etc. There would not necessarily be an issue with a CRO monitoring sites they selected for the study. If a sponsor chooses to cover all its own regulatory responsibilities, they would have in-house or contracted monitors who monitor the sites they have selected. To avoid a conflict of interest, the sponsor or the CRO responsible would ensure that the monitor does not report to the same department/division that chooses the sites. There will usually be company standard operating procedures (SOPs) in place that spell this out for the specific reason of avoiding even the appearance of a conflict of interest. So if the CRO is the investigator he would be monitoring his own studies.

Additionally, contract research organizations are mentioned in the link below. This new FDA document release in March 2011 outlines what may happen should an FDA inspection occur of a CRO. You will find this document helpful.

http://www.fda.gov/downloads/ICECI/EnforcementActions/BioresearchMonitoring/UCM133770.pdf

CROs are also mentioned in ICH-E6 Guidance on Good Clinical Practice --in section 5.2, page 24. See the link below

http:///www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf

Please see the guidance document on a Risk-Based Approach to Monitoring

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

Also Protecting the Rights, Safety, and Welfare of Study Subjects

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf

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

Kind regards,

Doreen M. Kezer, MSN
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Office of Good Clinical Practice
Office of the Commissioner, FDA



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**From:** [redacted]
**Sent:** Friday, September 19, 2014 1:15 AM
**To:** OC GCP Questions
**Subject:** Advice on Sponsor transfer of responsibilities to a phase I unit

Hi,

I would be grateful for advice on how a small or virtual biotechnology company with limited or no in house quality processes associated with being a sponsor should work with Phase I units (in particular). Is it acceptable to delegate the Sponsor obligations, assuming it is appropriately documented, to the Phase I CRO when the Phase I CRO is also fulfilling the role of investigator? How is this potential conflict handled?

Thanks