From: OC GCP Questions
To: [redacted]
Subject: Multi specialty group of physicians
Date: Thursday, May 29, 2014 3:10:34 PM

Good afternoon --

I am not sure that I understand your question. However, here is some information on CROs and SMOs.

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.

SMO's duties and responsibilities should be clearly stated and described in writing.

SMOs are mentioned in the guidance link below - Protecting the Rights, Safety, and Welfare of Study Subjects

http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm127740.pdf It states --

What are an Investigator's Responsibilities for Oversight of Other Parties Involved in the Conduct of a Clinical Trial?

a. Study staff not in the direct employ of the investigator

The staff involved directly in the conduct of a clinical investigation may include individuals who are not in the direct employ of the clinical investigator. For example, a site management organization (SMO) may hire an investigator to conduct a study and provide the investigator with a study coordinator or nursing staff employed by the SMO. In this situation, the investigator should take steps to assure that

the staff not under his/her direct employ are qualified to perform delegated tasks (see section III.A.1) and have received adequate training on carrying out the delegated tasks and on the nature of the study (see section III.A.2), or the investigator should provide such training. The investigator is responsible for supervision of the study tasks performed by this staff, even though they are not in his/her direct employ during the conduct of the study (see section III.A.3) and this responsibility exists, no matter how qualified and experienced these staff members are. In the event that the staff's performance of study-related tasks is not adequate and cannot be made satisfactory by the investigator, the investigator should document the observed deficiencies in writing to the staff's supervisor(s). Depending on the severity of the deficiencies, the clinical trial may need to be voluntarily suspended until personnel can be replaced.

b. Parties other than Study Staff

There are often critical aspects of a study performed by parties not involved directly in patient care or contact, and not under the direct control of the clinical investigator. For example, clinical chemistry testing, radiologic assessments, and electrocardiograms are commonly done by a central independent laboratory retained by the sponsor or the investigator. Under these arrangements, the central laboratory usually provides the test results directly to the sponsor and to the clinical investigator. Because the activities of these parties are critical to the outcome of the study, and because the sponsor retains the services of the laboratory, the sponsor is responsible for seeing that these parties are fulfilling their responsibilities for the study.

Less frequently, a study may require that clinical investigators arrange to obtain information critical to the study that cannot be obtained at the clinical investigator's facility. For example, if the study protocol requires testing with special equipment or expertise not available at the clinical investigator's facility, the investigator might make arrangements for someone outside the facility to perform the test. In this case, the results are provided directly to the clinical investigator, who then submits the information to the sponsor. Where such assessments are retained by the investigator, the investigator should take steps to ensure that the facility is adequate (e.g., has the required certifications or licenses). The investigator may also institute procedures to ensure the integrity of data and records obtained from the party providing the information (e.g., a process to ensure that records identified as coming from the party are authentic). Procedures are particularly important when assessments are crucial to the evaluation of the efficacy or safety of an intervention or to the decision to exclude subjects who would be exposed to unreasonable risk.

Clinical investigators should carefully review the reports from these external sources for results that are inconsistent with clinical presentation. To the extent feasible, and considering the specifics of study design, the clinical investigator should evaluate whether results appear reasonable, individually and in aggregate. If clinical investigators detect possible errors or suspect that results from a central laboratory might be questionable, the investigator should contact the sponsor immediately.

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

Kind regards,

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Office of the Commissioner, FDA

-----Original Message-----
From: [redacted]

Sent: Wednesday, May 28, 2014 8:45 PM
To: OC GCP Questions
Subject: Multi specialty group of physicians

Hello

I have some questions regarding documentation needed for an outside entities paperwork that is needed for clinical trials performed by a site management office.