From: OC GCP Questions
To: [redacted]
Subject: Questions relating to Agreements with Suppliers contracted to perform a Clinical Trial
Date: Tuesday, April 21, 2015 10:50:45 AM

Good morning –

FDA does not have specific guidance on vendors and suppliers in clinical trials and therefore some of your questions can not be answered. However, the Clinical Trial Agreement is a negotiated contract between the sponsor and the clinical investigator or research institution. The contract should ensure compliance with all applicable laws and regulations relating to the conduct of the study, good clinical practice, health information privacy, etc. Your legal counsel would be best to answer your questions regarding when the contract becomes valid as FDA cannot offer legal advice and does not give advice on agreements between sponsors and suppliers. It is best to speak to your legal counsel regarding your study trial agreements.

That said FDA regulations under 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.

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

If you have specific questions regarding a particular study, you may contact the FDA review division overseeing the study or the Center for Drugs (CDER) directly at druginfo@fda.hhs.gov. They will most likely contact the regulatory project manager if your study is under IND.

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
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Tuesday, April 21, 2015 9:09 AM
To: OC GCP Questions
Subject: Questions relating to Agreements with Suppliers contracted to perform a Clinical Trial

Dear Sir, Madam,

I am writing to you today in order to get a better understanding of the requirements from the FDA regarding Good Clinical Practice and especially regarding the Agreements signed between a Pharmaceutical Company or a Sponsor and a Third-party vendor contracted to perform part of a Clinical Trial or deliver Services necessary to perform a Clinical Trial or deliver Services in connection with the Approval of a Drug.

After reading the 21 CFR Part 11 I am not quite sure still if it is required to keep an Agreement signed between a Sponsor and a Supplier for each Project.

For example, if a Sponsor has a Master Services Agreement in place with a CRO to deliver fully outsourced Clinical Trials, does the Sponsor need to put in place a Project Agreement with the CRO for each separate Clinical Trials (taking into account that the Master Services Agreement covers the Services for every Clinical Trials)? If yes, does this Project Agreement need to be signed by both Parties or can a Purchase Order raised against this Project Agreement can act as a written agreement between the Parties for this specific Project and supersede the signature of the Project Agreement itself? Finally, for or how long shall a Sponsor keep a record of such Agreement in its systems?

Following my questions above, does these also apply to the contracts for the following Services to be used during a Clinical Trial:

- Supplier of Medical Devices (e.g. ECG, ePRO)
- Supplier of Data Management
- Supplier of Medical Affairs, Payer Evidence or Health Economics Services (e.g. global reimbursement dossier, economic model, burden of illness…etc.)
- Supplier of Medical Writing services

I would gladly appreciate to have a reply to these questions which might help us to drive simplification in our activities.

Also, I understand that my questions can be hard to reply to in an email and therefore, I will be happy to organize a Teleconference with a member of the OGCP if necessary.

I look forward to hearing from you.

Best

[redacted]