From: OC GCP Questions
To: [redacted]
Subject: Post FDA Inspection of Clinical Site
Date: Tuesday, April 21, 2015 11:32:45 AM

Good morning –

The investigator is encouraged to send any response to a 483 to the district office that the inspector came from. He/She should find that contact information at the top of the 483 form. He/she should try to respond as soon as possible after the close of the inspection (preferably within 15 days) so that the response can also be shared by the district office with the appropriate Center that issued the inspection assignment. It is the reviewing Center that will review the inspection report and make a final inspection outcome determination so it is best for the Center to have a copy of any response to the 483. Once a response is received by the district office, it should be shared by the district with the Center. You might want to suggest the CI include a request in his/her response to ensure that the response is shared with the appropriate Center.

There is not requirement from an FDA perspective to share the 483 and the response with the sponsor. However the sponsor most likely knows that an FDA inspection occurred at the site.

Sponsor responsibilities are to secure clinical investigator compliance. The regulations state under 312.56(b)

(b) A sponsor who discovers that an investigator is not complying with the signed agreement (Form FDA-1572), the general investigational plan, or the requirements of this part or other applicable parts shall promptly either secure compliance or discontinue shipments of the investigational new drug to the investigator and end the investigator's participation in the investigation. If the investigator's participation in the investigation is ended, the sponsor shall require that the investigator dispose of or return the investigational drug in accordance with the requirements of 312.59 and shall notify FDA.

You might find these documents useful.

http://www.fda.gov/downloads/ICECI/EnforcementActions/BioresearchMonitoring/UCM133773.pdf

http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126553.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
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Tuesday, April 21, 2015 9:32 AM

To: OC GCP Questions
Subject: Post FDA Inspection of Clinical Site

To whom it may concern,
I am a paralegal at a pharmaceutical company and just needed some information.

If the FDA issues a Form 483 "Notice of Observation" relating to a clinical study at a site, does the site have to send a copy of such notice of Form 483 along with sites response to the Form 483 to Sponsor for review prior to sending to the Form 483 to the FDA?

I will greatly appreciate any guidance you can provide on this.
Thanks

[redacted]