Clinical Research AuditFrom: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Tuesday, October 04, 2005 12:42 PM
To: [purged]
Subject: RE: Clinical Research Audit

Dear Mr. [purged]

Your questions to the GCP Questions e-mail account was forwarded to me for a response.

If a site has concerns about an individual investigator, the site may contact the local district office of the Food and Drug Administration to communicate those concerns. However, the choice of which FDA investigator will inspect a particular site is completely up to the district office. If you need to locate the name and address of the Director for a particular District Office, information about the regional and district offices are posted on the webpage for FDA's Office of Regulatory Affairs (http://www.fda.gov/ora/about/default.htm).

You also asked what a clinical research site can do to challenge findings listed on the Form FDA 483.

In general, if the FDA investigator observes any practices that, in his/her judgment, are deviations from FDA's regulations for the conduct of clinical studies or the protection of human subjects, the FDA investigator will issue a Form FDA 483 to the clinical investigator.

The FDA investigator also will prepare a narrative Establishment Inspection Report (EIR) that summarizes the inspection (e.g., the names and titles of the individuals who were interviewed at the site, which records were examined, the most responsible party at the firm, a summary of the FDA investigator's findings, etc.). The FDA investigator sends the EIR to the FDA Center that issued the inspection assignment, along with a copy of the 483 that was issued and any pertinent exhibits or attachments to support the 483 observations.

During the closing interview with the clinical investigator, the FDA investigator will go over all of the items on the 483 and allow the clinical investigator an opportunity to provide an oral response. The FDA investigator includes a summary of the closing interview in the EIR. Some clinical investigators also choose to respond to the 483 in writing, but this is not required. If a clinical investigator should choose to respond in writing, the correspondence would become part of the official file related to the inspection.

The Center reviews the materials submitted by the FDA investigator, including any post-inspection correspondence, and classifies the inspection, as follows:

An inspection is classified "NAI" (No Action Indicated) if during the inspection, the FDA investigator found no deviations from FDA's regulations. [No 483 would be issued in this situation.]

An inspection is classified "VAI" (Voluntary Action Indicated) if FDA investigator found deviations from the regulations, but the problems can be corrected by voluntary action on the part of the inspected firm.

An inspection is classified "OAI" (Official Action Indicated) if the investigator uncovered serious deviations from the regulations. A titled letter would be sent to the firm (Warning Letter). The firm must respond to the letter within a specified time frame, and must explain how they intend to correct the problems so that the problems do not happen again. In cases of serious non-compliance by a clinical investigator, FDA may initiate disqualification proceedings against the clinical investigator. In these instances, a "Notice of Initiation of Disqualification Proceedings and Opportunity to Explain (NIDPOE)" is issued. If the clinical investigator does not provide a satisfactory response, the agency will provide the clinical investigator with the opportunity for a regulatory hearing on the matter.

So, the short answer to your question is that an inspected firm is given the opportunity to respond orally to the items on the 483 at the closing interview, and may also respond in writing if the firm chooses to do so. The inspected firm may also respond to FDA's post-inspection correspondence, but is only required to do so if FDA has issued a titled letter to the firm (i.e., Warning Letter or NIDPOE).

Here is a link to the Office of Regulatory Affairs' Field Management Directive #145, which summarizes the procedures for release of EIRs to the inspected establishment, once the inspection has been closed:
http://www.fda.gov/ora/inspect_ref/fmd/fmd145.html . A copy of the EIR may also be obtained through the Freedom of Information Act. If you need information on how to submit a FOIA request, the information is posted on FDA's FOI website at the following URL:
http://www.fda.gov/opacom/backgrounders/foiahand.html .

I hope this is helpful.
Sincerely,
Carolyn Hommel
Consumer Safety Officer
Good Clinical Practice Program
Office of Science and Health Coordination
Office of the Commissioner

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This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

-----Original Message-----
From: [purged]
Sent: Monday, September 26, 2005 1:53 PM
To: GCPQuestions@OC.FDA.GOV
Subject: Clinical Research Audit

I am preparing a paper for an upcoming presentation and was told that I could get answers to my questions from this site.

Question #1

If a Clinical Research Site, that conducted IRB approved Clinical Research Trials, is contacted by the FDA concerning the scheduling of an upcoming inspection/audit at the site by an inspector who the site has audited the site in the past and the site is concerned about the "knowledge" that the inspector has regarding clinical research, is the site allowed to request a different inspector?

Question #2

If the answer to the above questions is "Yes" what is the exact procedure the site would have to follow in order to request the change of inspector?

Question #3

If a Clinical Research Site receives a Form 483, for an issue that an FDA inspector has reported yet is determined to be incorrect what options does the site have in order to challenge that finding?

Thanks for your help on these questions.

[purged]

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