From: Hommel, Carolyn - OC
Sent: Thursday, November 04, 2004 9:21 AM
To: [purged]
Subject: RE: PRIM&R Meeting Questions

Dear Ms. [purged]:

This is in response to your November 2 e-mail to Dr. David Lepay. I have pasted your questions into this e-mail and will answer each in turn.

1. What role/responsibility does an institution have in monitoring compliance of 21 CFR 54 in an industry sponsored study in which their physicians are clinical investigators?

Answer: FDA's regulations pertaining to "Financial Disclosure by Clinical Investigators," contained in 21 CFR 54, require clinical investigators to provide information about their financial interests to the sponsor(s) of the covered studies. The sponsors, in turn, are required to forward the information to FDA, either by certifying to the absence of such interests or by disclosing those interests when they are of certain types or reach specific monetary thresholds. In answer to your question, FDA's regulations do NOT require institutions to monitor the compliance of the clinical investigator(s) in providing information to the sponsors about their financial interests.

You can view FDA's regulations and financial disclosure guidance on FDA's Good Clinical Practice website (http://www.fda.gov/oc/gcp).

Nevertheless, recognizing that institutions and IRBs may want to eliminate, minimize, and manage potential conflicts of interest, the Department of Health and Human Services, Office for Human Research Protections recently issued "Guidance on Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection." The purpose of the guidance is to provide points to consider for institution/IRB staff who are wrestling with these questions, and trying to develop their own procedures for dealing with potential conflicts of interest stemming from financial relationships. There is a link to this guidance on FDA's website, shown above.

2. What is the maximum length of time it would take to receive a determination letter from the FDA after a 483 was issued and a response submitted by the investigator?

Answer: There is no statutory time limit for the agency to send a letter to an inspected firm after the inspection is completed and a 483 issued.

In the case of inspections pertaining to bioresearch monitoring (BIMO) facilities (e.g., sponsors, monitors, contract research organizations, institutional review boards, and clinical investigators), the responsibility for evaluating and classifying the inspection and issuing post-inspection correspondence resides with the FDA Center that issued the inspection assignment.

For other types of establishments, the Office of Regulatory Affairs (ORA) has issued some guidance on recommended time frames for Warning Letters issued by FDA's field offices. There are no time frames, however, for issuing untitled letters. ORA's guidelines, contained in the "Regulatory Procedures Manual (RPM)," may be viewed online at ORA's website (http://www.fda.gov/ora). Here is a link to Chapter 4 of the RPM pertaining to "Procedures for Warning Letters and Untitled Letters": http://www.fda.gov/ora/compliance_ref/rpm/pdf/ch4.pdf .

I hope this information is helpful.

Sincerely,

Carolyn Hommel
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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: Tuesday, November 02, 2004 4:37 PM
To: dlepay@oc.fda.gov
Subject: PRIM&R Meeting Questions

Dear Dr. Lepay:

I included in my choice of sessions at the PRIM&R conference the
"Non-Compliance: An Opportunity to Question the Federal Experts" with the intention of seeking guidance from a representative of the FDA. I was disappointed by the session because I was not able to speak with a representative of the FDA. I would appreciate it if you could direct me to obtaining such guidance based on the following questions:

1. What role/responsibility does an institution have in monitoring compliance of 21 CFR 54 in an industry sponsored study in which their physicians are clinical investigators?

2. What is the maximum length of time it would take to receive a determination letter from the FDA after a 483 was issued and a response submitted by the investigator?

Thank you for your time.

Sincerely,

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