From: Breen Block, Patricia
Sent: Friday, October 13, 2006 10:40 AM
To: [purged]
Subject: RE: GCP questions

Dear Mr. Wolfe,

Your inquiry was forwarded to our office for a direct reply. Unfortunately Stan Woollen no longer works for the FDA so I cannot definitively determine the answers he provided during his presentation. However I am confident that his reply would have been along the line that the investigator who signs the Form FDA-1572 assumes the regulatory responsibility to "personally conduct or supervise the described investigation(s)" [21 CFR 312.53(c)(1)(v)(c)]. It would be the investigator who signed the 1572 who would be held responsible for ensuring that a study is properly conducted. This investigator could be the recipient of an FDA letter if evidence was found that the study was not properly conducted (e.g., the investigator did not supervise the other 9 subinvestigators). The investigator could be found to have failed to meet the regulatory requirement that he/she will personally conduct or supervise the investigation identified in the 1572.

Regarding your question about reporting responsibilities, 21 CFR 312.56(b) requires that the sponsor report information about non-compliance and termination of an investigator's participation in a study to the FDA. The sponsor can certainly use information acquired by a contract monitor as a basis for making a conclusion that study was not being conducted in accordance with the investigational plan or the appropriate regulatory requirements governing clinical studies.

I hope this information is helpful to you.

Sincerely,

Patricia M. Breen Block
Good Clinical Practice Program (HF-34)
Office of Science and Health Coordination
Office of the Commissioner/ FDA
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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: Wednesday, September 27, 2006 3:59 PM
To: CDER DRUG INFO
Subject: DrugInfo Comment Form FDA/CDER Site

Name: [purged]

E-Mail: [purged]

Comments: Hello.

I am a monitor for a CRO and would like to know the following in reference to Case # 3 in Steven Woolen's slide show posted on your site (www.fda.gov/cder/present/da-62000/woolen2/woolen2.PPT).

What are the actual answers to these questions he poses in his slides:

When study monitoring has been contracted out, who is responsible for meeting the requirements of 312.56 (b) to report to FDA when an investigator is terminated for noncompliance?

What if the investigator is not terminated?

Many thanks- [Purged]