From: Toth-Allen, Jean
Sent: Thursday, May 18, 2006 8:54 AM
To: [purged]
Subject: RE: SI Monitoring

Dear [purged],

Despite the various scenarios you pose, the official responsibilities for the investigator are the same if that individual has agreed to be the sponsor of the IDE obtained from FDA (or, for NSR or exempt studies, by IRB approval of the study). FDA only looks at who is the official study sponsor which, in all scenarios you propose, would be the sponsor-investigator. The other relationships are all business contracts which FDA does not get involved with. The only one FDA would even need to know about is the monitor if a CRO was hired. We would, however, not care who was actually paying them for their monitoring services. We could also potentially inspect that CRO with regard to the study.

Hope this information is useful.

If you need further information and/or have additional questions, please submit them once again to the official GCP mailbox, gcpquestions@oc.fda.gov, in lieu of responding to my personal e-mail address.

Sincerely yours,
Jean Toth-Allen, Ph.D.
Good Clinical Practices Program
OSHC, Office of the Commissioner, US FDA

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: Thursday, May 11, 2006 3:30 PM
To: Toth-Allen, Jean
Subject: RE: SI Monitoring

Dear Jean,

I hope you are well. I wonder if you might be of assistance with some additional interesting questions I have been receiving relative to sponsor-investigators.

I've had questions from various parties regarding Sponsor-Investigator (SI) studies whereby funding is provided by the device company.

In one specific scenario, the company has entered into a contract with an investigator who will sponsor a study using the company's approved product for investigational research and the SI will be provided with funding from the company. There is no intent for the SI to provide the data to the company during the study. Since the company is providing funding and the company is knowledgeable about the study protocol, it is unclear whether the company has any obligations to obtain data (e.g., AEs) for reporting to their own approved application or whether it is acceptable that only the SI obtain the study data and report it to the investigational application as required by regulation.

In another specific scenario, the company contracts an investigator to sponsor and conduct study. Company contracts CRO to perform the data management. Company contracts third-party to monitor the study. Company assists in the development of protocol, consent form, case report forms, and other key documents. Company provides funding to the investigator. Investigator is responsible for the actual compilation of documents and submission of the application to the FDA. Investigator is responsible for maintenance of the application and subsequent submissions to the Agency.

While the regs are clear regarding the SI's obligations, can you please clarify what if any obligations the device company has:

1. Device company provides funding or other support to the SI and intends to receive data during the study.

2. Device company provides funding or other support to the SI but does not intend to receive data during the study.

3. Device company may or may not provide funding or other support to SI, does not intend to receive data during the study but is then provided with information about the study.

Your input would be greatly appreciated.

Kind Regards,

[purged]

-----Original Message-----
From:[purged]
Sent: Friday, March 31, 2006 4:29 PM
To: Toth-Allen, Jean
Subject: RE: SI Monitoring

Jean,

Thank you very much for your prompt response. I forwarded your email to the party requesting the information. As you probably know, our clients sometimes want to hear it right from the FDA. I agree with your input and find it perfectly reasonable and in their own best interest to ensure they are on track with the performance of their investigation. Thanks again for taking the time to respond in detail. Your input is greatly appreciated and very useful.

Kind Regards,

[purged]

"Toth-Allen, Jean" <jean.toth-allen@fda.hhs.gov> 03/31/2006 07:41 AM	To [purged] cc Subject RE: SI Monitoring

Dear [purged]:

Thank you for your inquiry regarding sponsor-investigators and monitoring responsibilities.

As you note, sponsor-investigators are regulated as both sponsors and investigators and study monitoring is a sponsor responsibility required by the regulation governing studies with investigational devices - Investigational Device Exemptions, 21 CFR part 812. FDA is aware that it is difficult for sponsor-investigators to ensure proper monitoring of their own studies. While not specified in the regulations, it is preferable to have someone independent of the study as the study monitor, as monitoring is intended to provide a system of checks and balances. A colleague who is familiar with and/or has participated in clinical investigations, an independent contract research associate (CRA) with specific monitoring credentials, or a professional contract research organization (CRO) are possible choices for an independent monitor for such studies.

Hope this information is useful.

If you need further information and/or have additional questions, please submit them once again to the official GCP mailbox, gcpquestions@oc.fda.gov, in lieu of responding to my personal e-mail address.

Sincerely yours,
Jean Toth-Allen, Ph.D.
Good Clinical Practices Program
OSHC, Office of the Commissioner, US FDA

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-----Original Message-----
From: [purged]
Sent: Monday, March 20, 2006 2:05 PM
To: OC GCP Questions
Subject: SI Monitoring

Dear FDA Representative,

An MD has expressed interest to a company in conducting a
sponsor-investigator (S/I) IDE with one of the company's approved products
for a new intended use.
In that the sponsor is also the investigator, what are the expectations
regarding monitoring?

Your feedback will be greatly appreciated.

Thank you,

[purged]