From: Toth-Allen, Jean
Sent: Tuesday, March 07, 2006 8:23 AM
To: [purged]
Cc: CDER DRUG INFO
Subject: RE: DrugInfo Comment Form FDA/CDER Site

Dear Ms. [purged]:

Thank you for your inquiry regarding investigator initiated studies.

If an individual investigator applies for and obtains an IND to conduct a pharmaceutical study, that individual is responsible for both sponsor and clinical investigator regulatory requirements. However, as with any trial, responsibilities can be contracted to others. Financial arrangements regarding supply of the investigational product and/or any other support, are not regulated by FDA. However, if someone chooses to arrange for monitoring and/or coverage of any other sponsor responsibilities (e.g., protocol development), there should be a contract spelling out exactly what responsibilities have been assumed by whom. Regulatory responsibilities transfer to those covering the contracted responsibilities, as stated at 312.52.

Hope this information is useful.

If you need further information and/or have additional questions, please submit them 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.
De
-----Original Message-----
From: [purged]
Sent: Friday, March 03, 2006 1:19 PM
To: CDER DRUG INFO
Subject: DrugInfo Comment Form FDA/CDER Site

Name: [purged]

E-Mail: [purged]
Comments: In the context of an investigator-initiated study, could you please tell me whether the drug company will have any liability or obligations with respect to the study if the drug company (1) arranges for monitors and GCP support and provides financial support for the trial, or (2) helps to formulate the protocol for the trial.

Thank you!