From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Wednesday, May 18, 2005 12:07 PM
To: [purged]
Subject: RE: DrugInfo Comment Form FDA/CDER Site

Dear Mr. [purged]:

There isn't any official guidance on how the 1572 should be completed, so there isn't any "right" answer, per se.

One possible way to make sure that everyone is aware of their arrangement would be for the two investigators to each sign a separate 1572 and list the name of the other investigator also in block 1, along with a statement that they are working together and equally sharing all responsibility for the conduct of the study at the site.

I would NOT recommend that they list each other as sub-investigators. That would be very confusing, and could make it appear that neither one is responsible.

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
U.S. Food and Drug Administration (HF-34)
5600 Fishers Lane, Room 9C24
Rockville, MD 20857

Phone: 301/827-3340
Fax: 301/827-1169

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, May 17, 2005 1:23 PM
To: gcpquestions@oc.fda.gov
Subject: RE: DrugInfo Comment Form FDA/CDER Site

Hello,

I hope that you might expand on the response received from CDER DrugInfo regarding completion of Form FDA 1572 in the event that a study site has co-investigators (please see attached previous emails).

One of our study sites has two principal co-investigators as well as several subinvestigators. The site intends that the two principal investigators will be equally responsible for the study at that site.

My specific question is:
If the co-investigators each complete a separate Form FDA 1572 (per instructions from CDER DrugInfo), should they list each other among the subinvestigators in section 6 of the form?

Thank you in advance for you kind assistance.

Regards,
[purged]

****
[purged]

"CDER DRUGINFO" <DRUGINFO@cder.fda.gov>
To: [purged]
cc:
Subject: RE: DrugInfo Comment Form FDA/CDER Site

05/12/2005
07:46

Thank you for your message to the Center for Drug Evaluation and Research (CDER), one of the five centers within the Food and Drug Administration (FDA).

The old form can be used if completed but revised forms should be used. The only difference in the forms is that the revised form has a different address to report comments to. The address is not relevant to the actual submission of the IND.

The following information is from our Office of Good Clinical Practice (GCP):

FDA regulations do not provide for co-investigators. Therefore, FDA would expect each clinical investigator to submit his/her own 1572 --- rather than a single 1572 that contains more than one designated investigator of record.

FDA GCP regulations and information related to the conduct of FDA regulated clinical trials can be accessed at the agency's Office for Good Clinical Practice web site (www.fda.gov/oc/gcp) this website also provides an e-mail
link for questions related to GCP.

Thank you
Bd100
CDER Drug Information

This communication is consistent with 21 CFR 10.85 (k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, 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, May 11, 2005 4:30 PM
To: druginfo@cder.fda.gov
Subject: DrugInfo Comment Form FDA/CDER Site

Name: [purged]

E-Mail: [purged]

Comments: Hello,

This two-part inquiry relates to Form FDA 1572.

1)In the event that a study site has co-investigators, is it permissible to list more than one individual as the investigator in section 1 of this form?

2)Will the 1/03 revision of the form be accepted by FDA if completed by the investigator after the implementation of the new revision (3/05)?

Thank you in advance for your response.
[purged]