From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Thursday, April 07, 2005 11:32 AM
To: [purged]
Cc: CDER DRUGINFO
Subject: RE: DrugInfo Comment Form FDA/CDER Site

Dear Mr. [purged]:

Your email, in which you asked if there is a technical definition that the FDA uses to describe the responsibilities of a sub-investigator on a clinical trial, was forwarded to me for a response.

The short answer is no--the Food and Drug Administration (FDA) definition of "sub-investigator" contained in the regulations is very general; it does not describe specific activities for which a sub-investigator may/should be made responsible.

FDA defines "Investigator" in 21 CFR 312.3(b) as "an individual who actually conducts a clinical investigation (i.e., under whose immediate direction the drug is administered or dispensed to a subject). In the event an investigation is conducted by a team of individuals, the investigator is the responsible leader of the team. "Sub-investigator" includes any other individual member of that team."

Likewise, FDA guidance documents provide only general descriptions of the duties/responsibilities that sub-investigators perform:

--The definition of "sub-investigator" in FDA's official guidance, the "ICH E-6 Good Clinical Practice: Consolidated Guidance," states: "Any individual member of the clinical trial team designated and supervised by the investigator at a trial site TO PERFORM CRITICAL TRIAL-RELATED PROCEDURES AND/OR TO MAKE IMPORTANT TRIAL-RELATED DECISIONS (e.g., associates, residents, research fellows)." [Emphasis added; see ICH Section 1.56; here's a link to the guidance: http://www.fda.gov/cder/guidance/959fnl.pdf]

--FDA's Guidance on Financial Disclosure for Clinical Investigators indicates that "sub-investigator" would include individuals who "MAKE DIRECT AND SIGNIFICANT CONTRIBUTIONS TO THE DATA." [Emphasis added; see Question/Answer #12 in "Guidance on Financial Disclosure for Clinical Investigators"; here is a link to the document that is posted on FDA's Good Clinical Practice website: http://www.fda.gov/oc/guidance/financialdis.html.]

It's important to recognize that any study staff who "make direct and significant contribution to the data" are considered "sub-investigators" under FDA's financial disclosure regulations (21 CFR 54), and thus would need to file financial disclosure information. They would also need to be listed in block #6 of the Form FDA 1572, which the sponsor must obtain from each clinical investigator prior to the start of a clinical investigation.

I hope this 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: CDER DRUGINFO
Sent: Wednesday, March 30, 2005 4:21 AM
To: OC GCP Questions
Subject: FW: DrugInfo Comment Form FDA/CDER Site

-----Original Message-----
From: [purged]
Sent: Tuesday, March 29, 2005 2:35 PM
To: druginfo@cder.fda.gov
Subject: DrugInfo Comment Form FDA/CDER Site

Name: [purged]

E-Mail: [purged]

Comments: I am interesting in find out if there is a technical defination that the FDA uses to describe the responsibilities of a sub-investigator on a clinical trial.

Thank you for the information