From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Wednesday, January 26, 2005 12:13 PM
To: [purged]
Cc: CDER DRUGINFO
Subject: RE: DrugInfo Comment Form FDA/CDER Site

Dear [purged],

We are frequently asked who should be listed on the 1572, and it's a question for which there is limited guidance and not always a straightforward answer. Many people do not realize that one of the main purposes of the 1572 is to provide the sponsor with information about the clinical site and investigator qualifications which will enable the sponsor to establish and document that the investigator and site are qualified to conduct the study.

Block #6 asks for the "Names of the subinvestigators (e.g., research fellows, residents, associates) who will be assisting the investigator in the conduct of the investigation(s)." "Subinvestigator" is indirectly defined in the drug and biologics regulations (21 CFR 312.3(b):

"Investigator means an individual(s) who actually conduct(s) a clinical investigation (i.e., under whose immediate direction the drug or biologic 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. 'Subinvestigator' includes any other individual member of that team."

Again, the purpose of block #6 is to capture information about those individuals who will play a key role in the collection, and interpretation of data, as well as in the conduct of the study itself. Hospital staff, including nurses, residents, or fellows and office staff who provide ancillary or intermittent care but who do not make direct and significant contribution to the data are generally not meant to be listed in block #6, and so a general statement regarding the participation of staff residents on rotation can be included in block #6.

Whether to list an individual depends on the level of responsibility the individual has in the conduct of the study and in the evaluation of information obtained during the study. If the individual in question has significant study related duties (e.g., explaining the study to subjects, qualifying the study subjects), then the person should be listed on the 1572. If the individual merely ensures and observes that, for example, a consent form is signed by the subject after the principal investigator has explained the study and qualified the subject, then this person would not have to be listed.

As for listing a pharmacist--that depends. Simply handling the study drug does not necessarily mean an individual should be listed in block #6. For example, a pharmacist who merely dispenses tablets and has no responsibility for preparing the test article or evaluating or reporting data relative to study activities need not be listed. However, if this pharmacist were compounding, labeling, monitoring, and reporting test article compliance data, then it may be appropriate to list this person on the form.

Information about clinical laboratory facilities to be used is captured in block #4; you do not need to list the heads of such labs in block #6.

Another thing to take into consideration when trying to decide if a person should be listed on the 1572 as either an investigator or subinvestigator is the fact that persons listed must disclose information about their financial interests, under FDA's regulations for "Disclosure of Financial Interests by Clinical Investigators" (21 CFR 54). These regulations define "clinical investigator" as any "listed or identified investigator or subinvestigator who is directly involved in the treatment or evaluation of research subjects. The term also includes the spouse and each dependent child of the investigator" (21 CFR 54.2(d). Question 12 of FDA's financial disclosure guidance (http://www.fda.gov/oc/guidance/financialdis.html, specifically addresses this issue.

This is kind of a long-winded response--I hope it answers your questions.

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: Monday, January 24, 2005 4:04 PM
To: OC GCP Questions
Subject: FW: DrugInfo Comment Form FDA/CDER Site

-----Original Message-----
From: [purged]
Sent: Thursday, January 20, 2005 3:07 PM
To: druginfo@cder.fda.gov
Subject: DrugInfo Comment Form FDA/CDER Site

Name: [purged]

E-Mail: chaikigr@umdnj.edu

Comments: I have a question about form FDA 1572. In section 6, names of subinvestigators, could you please clarify if the names of the research coordinators should be included? Should the pharmacist who dispences the study drug be listed? It says on the form to include any subinvestigator who will be assisting the investigator in the conduct of the investigation. Does the head of the laboratory of the local and central lab need to be included? All of these people assist the physician in the conduct of the investigation, but are not necessarily subinvestigators. I have never been able to get a straight answer to this question. Please be as clear as possible in your response.

Thnaks you,
[purged]