questionFrom: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Monday, December 05, 2005 11:58 AM
To: [purged]
Subject: RE: question

Dear Mr. [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):

> "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." 21 CFR 312.53(c)(1)(viii) requires the investigator to provide "A list of the names of the subinvestigators (e.g., research fellows, residents) who will be assisting the investigator in the conduct of the investigation(s)."

The purpose of Block #6 is to capture information about individuals who, as part of an investigative team, will be assisting the investigator and who make a direct and significant contribution to the data. The decision to list an individual in Block #6 depends on his/her level of responsibility (i.e., whether he/she is performing significant study-related duties). In general, if an individual is directly involved in the treatment or evaluation of research subjects, that person should be listed on the 1572. For example, as part of the protocol of a clinical investigation, if each subject needs to visit a specified internist who will perform a full physical to qualify subjects for the study, that internist should be listed in Block #6.

Hospital staff, including nurses, residents, or fellows and office staff who provide ancillary or intermittent care but who do not make a direct and significant contribution to the data do not need to be listed individually. It is not necessary to include in this block a person with only an occasional role in the conduct of the research, e.g., an on-call physician who temporarily dealt with a possible adverse effect or a temporary substitute for any research staff. If a number of staff residents on rotation participate on the study, a general

statement regarding their planned participation may be included in Block #6

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, November 29, 2005 2:57 PM
To: gcpquestions@oc.fda.gov
Subject: question

Your input on the question below would be very much appreciated.

Q. Box #6 of the Form FDA 1572-Statement of Investigator calls 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)."
The examples provided are of what are likely other M.Ds "who will be assisting the investigator in the conduct of the investigation(s)." But, based on the role they will be playing in the trial, should other site staff be considered "subinvestigators" in some cases, such as the study coordinators, site nurses, and others who will be involved in the trial? In other words, are there ANY circumstances in which these individuals should be listed in Box 6 or elsewhere on the 1572, or is the FDA just looking for a listing of those who

will play a medical role (e.g., medical decision making, treatment decisions)?
Or should these staff specifically NOT be listed in Block #6?
Thanks and best regards,
[purged]