From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Monday, November 13, 2006 11:02 AM
To: **[Redacted]**
Subject: RE: whether to list a study coordinator on the 1572

Dear Ms. **[Redacted]**:

I apologize for the delay in responding to your e-mail.

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.

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.

So, in short, whether a study coordinator should be listed as a subinvestigator is dependent upon the nature of their contributions to the study, and that is a judgment call that the clinical investigator would have to make. I'm sorry I cannot be of more help.

Sincerely,

Carolyn Hommel
Consumer Safety Officer
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.

From: **[Redacted]**
Sent: Thursday, October 19, 2006 1:02 PM
To: OC GCP Questions
Cc: Hommel, Carolyn - OC
Subject:

Dear Ms. Hommel,

I would like information on a guideline or any document that has a specific mention on the fact that the study coordinator must be listed on the Form FDA 1572.

Thanks you.

[Redacted]