From: Beers Block, Patricia
Sent: Thursday, October 26, 2006 7:56 AM
To: **[Redacted]**
Subject: RE: study coordinator

Dear Ms. **[Redacted]**,

Your message was forwarded to me for a direct reply.

FDA's regulation at 21 CFR 312.3(b) states: "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 [ICH E3 Section 6; http://www.fda.gov/cder/guidance/iche3.pdf].

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

If a research coordinator is performing critical study functions and collecting and evaluating some study data, the coordinator should be listed in Block #6. If the research coordinator is only transcribing data and maintaining study files, the coordinator does not need to be listed.

I hope this information is helpful to you.

Sincerely,

Patricia M. Beers Block
Good Clinical Practice Program (HF-34)
Office of the Commissioner/ FDA
Telephone: 301-827-3340

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: **[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]