From: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Monday, November 14, 2005 1:15 PM
To: [purged]
Subject: RE: Question re 1572

Dear [purged],

Your message was forwarded to me for reply. This is one of the most common questions we receive, and one 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.

Line #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 line #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. 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 (i.e., whether they are 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, if the radiologist is interpreting the x-ray films and CT scans related to primary efficacy or safety endpoints, then listing the radiologist on the 1572, again, makes sense.

Another thing to take into consideration when trying to decide if a person should be listed in line #6 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 investigators" 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)). [FDA published a guidance document that explains the background and interpretation of the financial disclosure regulations. You can view the guidance document online at http://www.fda.gov/oc/guidance/financialdis.html.] Question 12 of FDA's financial disclosure guidance specifically addresses this issue.

In answer to your specific question, if a study nurse or coordinator is directly involved with the handling of subjects/subject data, I have generally recommended including him/her on the 1572. By so listing this person on the 1572, this person would also need to disclose information about their financial interests as discussed above.

I hope this information is helpful to you.

Sincerely,

Patricia M. Beers Block
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----Original Message----
From: [purged]
Sent: Friday, November 04, 2005 6:14 AM
To: [purged]
Subject: Question re 1572
Importance: High

Dear Ms [purged],

I have one more question regarding the topic who should be listed on the 1572 and would like to ask for your advice.

We do routinely ask our investigators to put on the 1572 also any study coordinator who is in charge of the informed consent process (total information, answering questions, signing the consent form) when no physician is involved, means no further signature from a site physician on the consent form.

By doing so we did experience some difficulties as some sites don't want to have the study coordinator listed. From my ethical perspective, the consent process is a very important part of the trial and the decision how and to which level of detail a patient is informed lies always with the person who is in charge of this process and based on the information given, the subject decides to take part or not.

Even if the medical decision to enrol the patient is with the investigator, both are decision makers from my point of view.

Could you please give us advice!

Thank you very much!

Best regards,

[purged]