From: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Friday, December 16, 2005 9:13 AM
To: [purged]
Subject: RE: DrugInfo Comment Form FDA/CDER Site

Dear Ms. [purged],

Your message was forwarded to our office for a direct reply. As you probably already know, there are only very limited instructions on how to complete the Form FDA-1572 (see FDA Forms web site at http://www.fda.gov/opacom/morechoices/fdaforms/cder.html).

The purpose of block #6 of this form is to capture information about individuals who, as part of an investigative team, will be assisting (or expected to assist) 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 with regard to the conduct of the study (e.g., 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 ion the 1572. For example, as part of the protocol of a clinical investigator, if each subject needs to visit a specified internist who will perform a full physical to qualify subject for the study, that internist should be listed in bloc #6.

In answer to your question about when a subinvestigator needs to complete a financial disclosure statement required by 21 FR 54, a financial disclosure statement must be prepared by that subinvestigator at or very close to the time the 1572 is signed by the clinical investigator. Under 21 CFR part 54 (Disclosure of Financial Interests by Clinical Investigators), a person listed or identified as an investigator or subinvestigator who is directly involved in the treatment or evaluation of research subjects must submit financial disclosure information. For purposes o the financial disclosure regulation, the term investigator also includes the spouse and each dependent child of the investigator and subinvestigator.

In answer to your question about later replacing the 1572 with one that only includes the names of subinvestigators, I believe this process could be problematic if the revised document "replaces" the original 1572 and the original form is no longer available. It is required by regulation that this form be signed by the clinical investigator before he/she participates in the study. Revising and actually replacing the original 1572 with the revised 1572 would necessities changing the date the clinical investigator signed the form; this date would reflect one well after the start of the study. This might lead to some problems should the original 1572, for some reason, be misplaced or destroyed. I believe it is acceptable to prepare a new 1572 with a revised list of subinvestigators **provided** the original 1572 (with the original signing date) is preserved.

I hope this is helpful to you.

Sincerely,

Patricia M. Beers Block
Special Assistant to the Director
Good Clinical Practice Program (HF-34)
Office of Science and Health Coordination
Office of the Commissioner
5600 Fishers Lane, Rm. 9C24
Rockville, MD
20857
Telephone: 301-827-3340

-----Original Message-----
From: CDER DRUGINFO
Sent: Wednesday, November 30, 2005 2:12 PM
To: OC GCP Questions
Subject: FW: DrugInfo Comment Form FDA/CDER Site

-----Original Message-----
From: [purged]
Sent: Monday, November 28, 2005 10:55 AM
To: CDER DRUGINFO
Subject: DrugInfo Comment Form FDA/CDER Site

Name: [purged]

E-Mail: [purged]

Comments: My question pertains to Section 6 of the Form 1572. At our CRO, our practice is to list the 5 sub-investigators who have responsiblities delegated to them in the absence of the Principal Investigator. This way, if any intervention is required in the absence of the PI, any of the 5 sub-investigators can be enlisted. Upon completion of the study, we revise section 6 so that only the sub-investigators who actually participated in the study (among the original 5 and any others) are listed on the form. This revised version supercedes the previous version(s) and is submitted with the final report. Additionally, only the sub-investigators who actually participate in the study are requested to sign a financial disclosure.

Could you please comment on whether or not our practices are acceptable?

Is there a need to have the 5 sub-investigators who are originally listed to sign a financial disclosure, even if they do not eventually participate in the study?

When additional sub-investigators (other than the 5 with delegated responsibilities) are enlisted, should the Form 1572 be revised prior to their involvement in the study, or does their signage of a financial disclosure prior to any involvement, and the later update of the 1572 suffice?

I look forward to your response.

Sincerely,
[purged]