From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Thursday, May 12, 2005 11:44 AM
To: [purged]
Cc: CDER DRUGINFO
Subject: Updating a 1572 when an investigator leaves a study

Dear Ms. [purged]:

Your question to the CDER DRUGINFO e-mail account about updating a Form FDA-1572 (1572) was forwarded to me for a response. You specifically asked if a 1572 must be updated when a sub-investigator is no longer affiliated with the study.

To answer your question, beyond reporting a new investigator (and the subinvestigators under them) as required by 312.30, I'm not aware of any specific requirement to revise the 1572 when a subinvestigator leaves the study.

The 1572 has two important functions. First of all, the 1572 is intended to provide the sponsor with information about the clinical site and investigator qualifications that will enable the sponsor to establish and document that the investigator and site are qualified to conduct the study. The second important purpose of the 1572 is to obtain the clinical investigator's commitment that he/she will conduct the study in accordance with the approved protocol, and will comply with all of the requirements for conducting such studies as set forth in 21 CFR 312, 50, and 56.

Many people are don't realize that the 1572 itself is not required to be submitted to FDA, although in practice, sponsors often submit the 1572 to the IND as an efficient means to provide the information required under 21 CFR 312.23(a)(6)(iii)(b):

"(b) The name and address and a statement of the qualifications (curriculum vitae or other statement of qualifications) of each investigator, and the name of each subinvestigator (e.g., research fellow, resident) working under the supervision of the investigator; the name and address of the research facilities to be used; and the name and address of each reviewing Institutional Review Board."

As you are probably aware, the sponsor is required to file an amendment to the IND under 312.30 when certain changes are made, including changes in a protocol (that would significantly affect the safety of subjects, the scope of the investigation, or the scientific quality of the study (21 CFR 312.30(b)), or the addition of a new investigator (21 CFR 312.30(c)), in which case the sponsor must submit the same information as described above (21 CFR 312.23(a)(6)(iii)(b)). Again a sponsor may elect to provide the 1572 for a new investigator as a means to report this information. But, as I mentioned before, I'm not aware of any specific requirement to revise the 1572 simply to report that a subinvestigator has left a study.

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: CDER DRUGINFO
Sent: Wednesday, May 11, 2005 5:00 PM
To: OC GCP Questions
Subject: FW: DrugInfo Comment Form FDA/CDER Site

-----Original Message-----
From: [purged]
Sent: Tuesday, May 10, 2005 8:14 PM
To: CDER DRUGINFO
Subject: DrugInfo Comment Form FDA/CDER Site

Name: [purged]

E-Mail: [purged]
Comments: Re: 1572 forms

Each time a sub-investigator leaves an investigational site, do we have to get a new 1572 form signed with that investigator deleted?