From: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Wednesday, February 23, 2005 2:21 PM
To: [purged]
Subject: RE: DrugInfo Comment Form FDA/CDER Site

Dear Ms. [purged],

Your message was referred to our office for a direct reply. You don't need to modify the 1572s at this time. One way to address this change is to prepare a document that lists all of the studies this person was identified as a subinvestigator and send this document to the appropriate sponsor(s) (keeping a copy for your own records). It is important that the sponsor(s) be aware of this change so it/they can notify FDA of this change.

I hope this information is helpful to you.

Sincerely,

Patricia M. Beers Block
Special Assistant to the Director
Good Clinical Practice Programs (HF-34)
Office of Science and Health Coordination
Office of the Commissioner

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: Thursday, February 10, 2005 10:45 AM
To: OC GCP Questions
Subject: FW: DrugInfo Comment Form FDA/CDER Site

-----Original Message-----
From: [purged]
Sent: Thursday, February 10, 2005 8:18 AM
To: druginfo@cder.fda.gov
Subject: DrugInfo Comment Form FDA/CDER Site

Name: [purged]

E-Mail: [purged]

Comments: A Sub Investigator at my site will be retiring next month. He has been listed on every 1572 form submitted to FDA. What is the correct procedure for removing his name from the 1572 forms and will I need to repeat this procedure for each 1572 his name was listed on? Our site will still be doing follow up for patients that were enrolled by this physician. Please advise.