From: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Wednesday, August 17, 2005 1:58 PM
To: [purged]
Subject: RE: DrugInfo Comment Form FDA/CDER Site

Dear Ms. [purged],

Your inquiry was referred to our office for a direct reply. If there are changes to information contained don the 1572 (e.g., an IRB address change, the addition of new subinvestigators, discontinuing the use of a clinical lab), the investigator should document the changes and inform the sponsor so that the sponsor can appropriately update the IND. The 1572 itself does not need to be revised and signed by the investigator.

I hope this information 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: Tuesday, August 09, 2005 12:22 PM
To: OC GCP Questions
Subject: FW: DrugInfo Comment Form FDA/CDER Site

-----Original Message-----
From: [purged]
Sent: Tuesday, August 09, 2005 10:52 AM
To: druginfo@cder.fda.gov
Subject: DrugInfo Comment Form FDA/CDER Site

Name: [purged]

E-Mail: [purged]

Comments: Could you please clarify the process/procedure involved in Form 1572 submissions - specifically, if we have a sub-investigator and a clinic site listed on the original submission, if during the course of the study there is a change such that the sub-inv leaves the site (and there are no current sub-inv at our site) and that the clinic site will no longer be used - Should the 1572 be revised and to include the deletions and signed by the investigator?

Best regards,

[purged]