From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Monday, April 11, 2005 10:23 AM
To: [purged]
Cc: Daciek, Barbara J
Subject: RE: DrugInfo Comment Form FDA/CDER Site

Dear Ms. [purged]:

Your question to the CDER DRUGINFO e-mail account on completing the 1572 was forwarded to me for a response.

The investigator's official address of record should be entered in block #1 of the 1572.

The address(es) of the location(s) where the investigation will be conducted and where the test articles will be shipped, if different from the investigator's official address of record, should be entered in block #3.

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

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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: [purged]
Sent: Wednesday, March 23, 2005 12:27 PM
To: druginfo@cder.fda.gov
Subject: DrugInfo Comment Form FDA/CDER Site

Name: [purged]

E-Mail: [purged]
Comments: My question relates to which address a PI should list in section 1 of the 1572. The study is currently active at Hospital A and this is the same facility where subjects are seen. The PI has maintained privileges at Hospital A but has now become an employee of Hospital B. The study is not active at Hospital B.

Should the PI list the address of Hospital A or Hospital B or any address where the PI would want to receive correspondence from the FDA?