1572 questionFrom: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Friday, January 14, 2005 3:18 PM
To: [purged]
Subject: RE: 1572 question

Dear Ms. [purged]:

The investigator's official address of record should be entered in item #1 of the 1572. The address(es) of the location(s) where the actual investigation will be conducted and where the test articles will be shipped should be entered in item #3.

If you have additional questions, please let us know.

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)
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-----Original Message-----
From: [purged]
Sent: Wednesday, January 12, 2005 11:10 AM
To: gcpquestions@oc.fda.gov
Subject: 1572 question

Hi There,
I am wondering what is the intent of Box 1 on the 1572. Box 1 simply asks for Name and Address of Investigator
We have an IRB who states that the site should list the address where subjects are seen/where research is conducted in Box 1 and that Administration or

business address be listed in box 3. However, the sites interpretation is that the business address of the PI be placed in Box 1, and then list all other related addresses in Box 3.
I can see both sides here and admit that the requirement of the box can be interpreted either way. Please advise what does the FDA look for in Box 1 of the 1572.
Many thanks!
[purged]