MessageFrom: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Friday, January 07, 2005 9:13 AM
To: [purged]
Subject: RE: Form FDA 1572

Dear Ms. [purged]:

Your letter to the CDER DRUGINFO e-mail account was forwarded to me for a response.

You may include information about the imaging facility (ies) in Section 4 of the 1572.

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: Thursday, January 06, 2005 11:59 AM
To: OC GCP Questions
Subject: FW: Form FDA 1572

-----Original Message-----
From: [purged]

Sent: Thursday, January 06, 2005 11:34 AM
To: DRUGINFO@cder.fda.gov
Subject: Form FDA 1572

Dear Drug Info Staff,
I was advised to contact you with this question by [purged] at the Forms Management office. Can you advise the correct place on Form FDA 1572 to include imaging facilities that will be performing scans on subjects? I am unsure whether the information should be included under Section 3, or Section 4 and considered a "laboratory" facility to be used in the study. The investigator is not affiliated with the imaging facility, and aside from the scan (e.g., MRI or CT scans), all clinical investigations will be conducted at the clinic address listed in Section 3.

Thank you for your help!

Sincerely,
[purged]