From: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Monday, February 13, 2006 7:30 AM
To: '**[Redacted]**'
Subject: RE: CT PET Scan
Dear **[Redacted]**,

If this procedure will regularly be conducted at one site, it's useful to include information in the Form FDA-1572 about the site. If this procedure is only intermittently conducted by a site, it would be better to identify the central lab or the site that is coordinating the selection/contracting of these other study sites on the 1572. Information about where testing will be done must be recorded in study records; this information must be available to an FDA investigator during an FDA inspection.

I hope this information is helpful to you.

Sincerely,

Patricia M. Beers Block
Good Clinical Practice Program (HF-34)
Office of the Commissioner/ FDA
Telephone: 301-827-3340

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: **[Redacted]**
Sent: Friday, February 03, 2006 2:45 PM
To: gcpquestions@oc.fda.gov
Subject: CT PET Scan

To Whom It May Concern:

A study requires a CT Pet scan for research purposes only. The scan will be done at a different site. Does that site need to be on the 1572 form? No other procedures will be conducted at the other site.

Thank you,
[Redacted]