From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Tuesday, May 31, 2005 11:01 AM
To: [purged]
Cc: CDER DRUGINFO
Subject: RE: DrugInfo Comment Form FDA/CDER Site

Dear Ms. [purged]:

Your question to CDER's DRUGINFO e-mail account about listing laboratories on the 1572 was forwarded to me for a response.

Block #4 on the 1572 is intended to identify clinical laboratories or testing facilities directly contributing to or supporting the clinical trial (for example, diagnostic labs performing blood work, imaging centers, cardiology labs, etc.). If a laboratory or testing facility is performing procedures required by the study protocol for collection of significant endpoint safety or efficacy data, then it should be listed.

Although you don't really say what the first lab is doing, other than that the samples are sent there "for processing," it would make sense to list all three to ensure that the sponsor knows the chain of custody for handling the samples.

I hope this answers your question.

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
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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: CDER DRUGINFO
Sent: Tuesday, May 24, 2005 1:43 PM
To: OC GCP Questions
Subject: FW: DrugInfo Comment Form FDA/CDER Site

-----Original Message-----
From: [purged]
Sent: Tuesday, May 24, 2005 1:14 PM
To: druginfo@cder.fda.gov
Subject: DrugInfo Comment Form FDA/CDER Site

Name: [purged]

E-Mail: pkennedy@Medsource.com

Comments: There are 3 labs that will process labs samples from 6 investigator sites in the study I am working on. The labs are drawn at the individual site then sent to another site for processing. Then they are sent to 2 other labs. I have requested that all labs involved in the processing be included on the 1572. Is this correct?

regards,

[purged]