From: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Tuesday, June 28, 2005 7:51 AM
To: [purged]
Subject: RE: 1572 Question

Dear [purged],

This is a question we receive with some frequency. It is our opinion that block #4 of the 1572 is intended to identify clinical laboratories or testing facilities that directly contribute to or support the clinical trial (e.g., 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 in block #4.

In the scenario you describe below, the central laboratory that analyzes the samples to meet study protocol requirements/procedures should be listed in block #4 of the 1572. The location of the medical center laboratory that collects the blood sample appears to already be identified in block #3 in that it is a part of the clinical laboratory facility. The medical center laboratory need not be identified in block #4 unless and until it performs analysis of biological samples at which time this lab should be added to block #4 of the 1572.

I hope this information is helpful to you.

Sincerely,

Patricia M. Beers Block
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Good Clinical Practice Program (HF-34)
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-----Original Message-----
From: [purged]
Sent: Saturday, June 18, 2005 1:05 PM
To: gcpquestions@oc.fda.gov
Subject: 1572 Question

Dear GCP Staff:

I have a question about placing laboratories on the FDA-1572. If a clinical site uses their own medical center laboratory to perform the blood draw, package and ship blood samples to a central clinical laboratory that performs all of the analyses for the study, does the medical center lab need to be on the 1572? The medical center laboratory does maintain a reserve sample, and phlebotomy/shipment records. Our current feeling is to only place laboratories on the 1572 if they perform analyses and generate clinical data.

Thank you,

[purged]