From: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Thursday, June 02, 2005 10:14 AM
To: REDACTED
Subject: RE: Question for Patricia Block.

Dear REDACTED,

I believe the key to this question is whether testing is done to meet study protocol requirements. When testing is done that is used to meet study protocol requirements, it is important to provide testing site information (name and address of the testing facility) to the sponsor (and ultimately to FDA) via the 1572.

I hope this additional clarification helps.

Sincerely,

Patricia M. Beers Block
Special Assistant to the Director
Good Clinical Practice Program (HF-34)
Office of Science and Health Coordination
Office of the Commissioner
5600 Fishers Lane, Rm. 9C24
Rockville, MD
20857

Telephone: 301-827-3340
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-----Original Message-----
From: REDACTED
Sent: Wednesday, May 25, 2005 7:36 PM
To: GCPQuestions@OC.FDA.GOV
Subject: Question for Patricia Block.

Dear Patricia M. Beers Block,
I have received this as a forward from a co-worker in response to a question as to if REDACTED labs are to be included on the 1572 form block #4. However, in your answer I am confused. On the one hand you say that block #4 is used to identify clinical laboratories or testing facilities "directly contributing of supporting" the clinical trial where the procedures required by the study protocol are for the collection of significant endpoint safety or efficacy data. I also agree that clearly that is the purpose of the form.

However, REDACTED data derived from REDACTED are utilized for research purposes only and are not for the purpose of providing a physician with real time data that can be used for diagnosis, prevention, treatment, or assessment of patient health. Therefore, a CLIA certificate of accreditation is not required for analyses in support of these types of studies. The FDA (and other regulatory agencies) inspects the REDACTED for these tests under the FDA Bioresearch Monitoring Compliance Program; however, a certificate of accreditation is not provided.

Therefore my understanding since the REDACTED data is not used for assessment of patient health or treatment, the REDACTED labs do not need to be on the 1572 forms. Could you please look into this further and clarify?

Many thanks.
Regards,
REDACTED

-----Original Message-----
From: OC GCP Questions <GCPQuestions@OC.FDA.GOV>
Sent: Tue, 10 May 2005 15:11:04 -0400
Subject: RE: Statement of Investigator: Form FDA 1572

Block # 4 is intended to identify clinical laboratories or testing facilities directly contributing or supporting the clinical trial (for example, diagnostic labs performing blood work, imagining 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 answer to your question, yes, the laboratory that is performing the analysis of REDACTED samples should be listed in block #4 on the 1572.

I hope this information is helpful to you.

Sincerely,

Patricia M. Beers Block
Special Assistant to the Director
Good Clinical Practice Program (HF-34)
Office of Science and Health Coordination
Office of the Commissioner
5600 Fishers Lane, Rm. 9C24
Rockville, MD
20857

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