From: OC GCP Questions
To: [redacted]
Subject: RE: Clinical laboratory testing guidance for clinical trials
Date: Monday, July 20, 2015 2:38:00 PM
Attachments:

[redacted],

Thank you for your inquiry. Please note that CLIA is administered by the Centers for Medicare & Medicaid Services (CMS), so that agency would be in the best position to respond to your questions. Information about CLIA can be found on the CMS website: http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html. In addition, for a list of state agency and regional office CLIA contacts who might be able to assist you further, please see: http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/State_Agency_and_Regional_Office_CLIA_Contacts.html.

I am not sure which draft GLP guidance you may be referring to, but I was able to locate one which is currently on FDA's webpage: The Applicability of Good Laboratory Practice in Premarket Device Submissions: Questions and Answers - Draft Guidance for Industry and Food and Drug Administration Staff (http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm366338.htm).

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

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From: [redacted]
Sent: Wednesday, July 15, 2015 12:37 PM
To: OC GCP Questions
Subject: Clinical laboratory testing guidance for clinical trials

Dear FDA HHS office,

I have tried to find the original CLIA regulations on the FDA.gov website and only find amendments related to Medical devices or diagnostic testing.

I know that the GLP regulations do not apply to clinical laboratory testing procedures for human subjects involved in clinical research trials. I need to find information on blood sample transport requirements, chain of custody for samples transported from a research site where the blood sample is drawn to the laboratory where testing is done. I know that IATA covers the transport from clinical sites or facilities to the laboratory, but does IATA cover transport from one site to another.

I am looking for something that not only address the safety aspect (pathogens, etc..) but more the sample integrity of the blood sample in transit. I have visited a site recently where they are transported from one site where they drew the sample across town to another site (their own) where they do the testing; they have no SOP or work instruction for the sample transit and they do not log what has been transported. There was at one time a draft document for Good Clinical Laboratory Practices, but I have not seen this lately. Could you please provide assistance and possibly direct me to the best guidance?

Kind Regards,

[redacted]

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