From: OC GCP Questions
To: [redacted]
Subject: Clinical laboratories supporting clinical trials
Date: Monday, October 05, 2015 6:41:01 AM

Good morning --

If you are performing testing on human subjects, that testing must be done in a lab that has an appropriate CLIA certificate (e.g., a waived certificate to use waived tests).

Additionally while a specific study protocol may require additional recordkeeping, if nothing is specified in the protocol the expectation is that the clinical laboratory that analyzes study samples/specimens will comply with the recordkeeping requirements of CLIA. In addition, the case report forms (CRFs) for the study subjects should contain information as to what specimens were sent for analysis, the date(s) they were both collected and sent, and any study-specific information regarding handling of the specimens and their transmittal to the laboratory and/or receipt of the results. If a bioresearch monitoring (BIMO) inspection was conducted at the site, FDA investigators would expect to see the original copies of protocol-specified laboratory results in each subject's study file and look to reconcile the dates on the results with the information in the CRFs. While FDA regulations do not address the chain of custody of study specimens, should there be any concerns about laboratory results for one or more study subjects, FDA would look for documentation of specimen collection, handling, shipment, etc. in search of potential causes of noted or suspected discrepancies.

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

Kind regards,

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Office of Good Clinical Practice
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From: [redacted]
Sent: Friday, October 02, 2015 3:08 PM
To: OC GCP Questions
Subject: Clinical laboratories supporting clinical trials

It is my understanding that the FDA does not have any specific regulations or guidance applicable to clinical laboratories supporting human clinical trials. We are a CLIA certified and CAP accredited molecular diagnostic laboratory. Please confirm that the standards developed by CMS under CLIA for certification of clinical laboratories would be acceptable to FDA. In addition, is there any circumstance in which a laboratory in the US would have to comply with European GCLP guidance?

Thanks very much for your advice.
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