From: OC GCP Questions
To: [redacted]
Subject: Question re Labs involved in Clinical trials
Date: Friday, October 30, 2015 12:59:48 PM

Good afternoon –

FDA expects that the laboratory is qualified to conduct the study and that the site has documentation of this fact. Anything you implement above and beyond the requirement of CLIA is up to you. Whether or not the laboratory is required to be certified or accredited will depend on local laws. In the US, high complexity clinical laboratories are subject to the Clinical Laboratory Improvement Act (CLIA) which is implemented by the Centers for Medicare and Medicaid (CMS), which requires certification (see www.cms.hhs.gov/clia/ for more information).

Additionally, 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,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Friday, October 30, 2015 12:01 PM
To: OC GCP Questions
Subject: Question re Labs involved in Clinical trials

To whom it may concern:

Thank you in advance for your time in answering my questions. I am doing research on behalf of a laboratory that is considering being in clinical trials sponsored by pharmaceutical companies.

My question is whether, in addition to CLIA, there are any federal statutes or regulations that dictate the responsibilities of a laboratory participating in a clinical trial?

I know that is a broad question but I'd appreciate it if you could at least point me in the right direction.

Thank you,

[redacted]