From: OC GCP Questions
To: [redacted]
Subject: GCP Sections for Laboratories
Date: Wednesday, September 24, 2014 1:39:58 PM

Good afternoon –

FDA regulations in 21 CFR Part 58 only address non-clinical laboratories.

FDA expects that the laboratories used to analyze clinical specimens for clinical trials be qualified. If the sponsor is using a central laboratory, it would be sufficient for them to retain documentation of the laboratory's qualifications, which usually includes background information on the director.

Specifics as to what documentation clinical laboratories need to retain is covered under the Clinical Laboratory Improvement Amendments (CLIA), which is under the purview of the Centers for Medicare and Medicaid (CMS) not FDA. Information about CLIA can be found at http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html?redirect=/clia/ and the current CLIA regulations can be accessed at http://wwwn.cdc.gov/clia/regs/toc.aspx.

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,

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

From: [redacted]
Sent: Tuesday, September 23, 2014 5:02 PM
To: OC GCP Questions
Subject: GCP Sections for Laboratories

Hello,

I am with a company who is contracted by clinical trial sponsors to perform analytical services on their clinical samples. We are looking to become GCP compliant and was wondering if you could point us to the sections of 21 CFR that would be specific (or most relevant) to our GCP compliance efforts.

Thank you.

[redacted]