From: OC GCP Questions
To: [redacted]
Subject: Lab Questions
Date: Tuesday, October 09, 2018 10:16:13 AM
Attachments: [redacted]

Good morning –

Although CLIA certification is not required for a clinical lab to participate in FDA-regulated research, it does represent a standard that is acceptable to FDA for the purposes of clinical diagnostic testing. FDA does not regulate clinical laboratories but does expect laboratories used for analysis of testing required as part of clinical studies to be qualified to do so. How this is documented (CVs and licensure) is up to the sponsor. In most cases, such testing is typical clinical testing and CLIA certification would provide ample proof that the laboratory is qualified. If specialized testing is required for a particular clinical trial, FDA would expect a sponsor to have documentation that the laboratory used is qualified to do such testing. FDA would only look at the laboratory findings if we found problems with the data and we would expect proper documentation that those involved would be qualified to perform the testing.

Kind regards,

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From: [redacted]
Sent: Thursday, October 04, 2018 2:00 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Lab Questions

In the US, collecting the lab director's CV, license and lab normals (when they are printed on the page alone with the results) seems to be a thing of that past, so I'm wondering why I still hear Sponsors collecting these items.

Do Sponsors need to collect a CV and medical license for the hospital laboratory director and lab normal values (when the normal values are printed on the page along with the results)? These hospital labs already have CAP certification and CLIA through CMS, and the normal values are printed along with the lab results.

What is the purpose of collecting lab director information when these certifications demonstrate the quality of the lab testing.

Thanks for any insight!

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