From: Brown, Sheila (OGCP)
To: [redacted]
Subject: RE: FDA Regulations - Laboratory Testing
Date: Monday, September 24, 2018 8:19:00 AM

Dear [redacted],
We recommend using laboratory tests that are cleared or approved by FDA, when available. More information about in vitro diagnostic testing can be found on FDA's website at https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/default htm . If you have questions about specific testing for a study, we recommend that you contact the review team for your submission.

I hope this information is helpful to you. If you need further assistance, please feel free to contact the GCP mailbox at gcp.questions@fda.hhs.gov .

Best regards,

Sheila

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-----Original Message-----
From: [redacted]
Sent: Thursday, September 20, 2018 2:40 PM
To: OC GCP Questions <gcpquestions@fda hhs.gov>
Subject: FDA Regulations - Laboratory Testing

I have a question with regards to the regulations that pertain to a CLIA laboratory participating in clinical trials. I understand the FDA recognizes CLIA, as overseen by CMS. More specifically, are there any additional requirements for the following types of laboratory testing in support of a clinical trial?

-primary and secondary endpoint/efficacy
-safety
-patient inclusion/stratification
-pharmacodynamic (PD)
-exploratory

Thank you for your time and clarity on this matter.