From: OC GCP Questions
To: [redacted]
Subject: Clia Waiver
Date: Friday, April 27, 2018 12:38:00 PM
Attachments: [redacted]

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). It might be best to contact CMS as I am not sure I know the answer to your question.

Kind regards,

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Office of Good Clinical Practice
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U.S. FOOD & DRUG ADMINISTRATION

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: [redacted]
Sent: Wednesday, April 25, 2018 5:32 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>; gcp.questions@fda.gov
Subject: Clia Waiver

If you have a clinical trial site in two locations, one primary site and and one satellite site, do you need a CLIA waiver for each facility?