From: OC GCP Questions
To: [redacted]
Subject: Samples question
Date: Thursday, August 23, 2018 8:58:00 AM

Good morning --

My office does not receive many questions on laboratory or sample collection. However, I can offer you the following information.

FDA does not have any regulations applicable to clinical laboratories supporting clinical trials, nor any requirements as to how a clinical laboratory should provide information, such as normal ranges, to clinical sites.

"Essential Documents" chapter of FDA's official guidance, the ICH E6(R2), "Good Clinical Practice: Consolidated Guidance, https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2__Step_4_2016_1109.pdf "states that sites and sponsors should maintain records of normal values/ranges for medical, laboratory, and technical procedures for tests included in the protocol (section 8.2.11), and certifications/accreditations to document the competence of the facility performing these tests (section 8.2.12), again, there is no specific detail as to how the clinical laboratory should provide this information to a study site.

Also there are a number of organizations, accreditation bodies, and other government agencies in the United States that have established standards for clinical laboratories. In the U.S., the principle government standard, enforced now by the Centers for Medicare and Medicaid Services (CMS), is CLIA certification. This is carried out under the Clinical Laboratory Improvement Act and applies to just about any clinical laboratory which carries out clinical testing (except for research) in interstate commerce. Although CLIA certification is not required for a clinical lab to participate in an IND study, it does represent a standard that is acceptable to FDA for the purposes of clinical diagnostic testing. To learn more about CLIA, you can visit their website at www.cms.hhs.gov/clia/

I hope this information is helpful.

Kind regards,

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

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, August 22, 2018 9:24 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Samples question

Good Morning,

I am looking for guidance on whether or not Sponsors are allowed to receive and process participant samples in-house. We are currently looking into an outside laboratory to run our samples but it was brought up that this may be something we could do in-house. Any guidance documents or personal guidance that could be provided on which route would be best practice would be very much appreciated. Thank you!

Best,