From: OC GCP Questions
To: [redacted]
Subject: Clinical Trial question
Date: Monday, May 01, 2017 9:53:00 AM
Attachments: [redacted]

Good morning –

FDA generally views clinical laboratory services as a contract function of the sponsor of a clinical trial. Any clinical laboratories used to provide significant support for, or contribute, data that are specified in the protocol, required by FDA, or intended for submission to FDA, should be identified in market applications. Significant support would include, for example, generating significant safety or efficacy endpoint data for the trial. Laboratories used by clinical investigators should be identified in Block #4 of the FDA Form 1572 ("Statement of Investigator") . This block is intended to identify clinical laboratories or testing facilities directly contributing to or supporting the clinical trial (for example, diagnostic labs performing blood work, imaging centers, cardiology labs, etc.). Therefore investigators should identify labs directly contributing to or supporting the clinical trial should in Block #4 of this form.

We do expect that the laboratory is qualified to conduct the study including the local lab and that the site has documentation of this fact. Documentation of the personnel training is very important. What FDA expects is that each clinical study site use a clinical laboratory that is qualified to do the clinical testing specified in the protocol. In the US, this will usually be a CLIA-certified laboratory. For some highly specialized tests, only a few laboratories may actually be qualified to perform the test, some based at academia or private laboratories that only do the test in question and therefore have no reason to hold a CLIA certification. Other documentation of their qualification to perform the specific test(s) would then be necessary.

So while not clearly stated in writing it would appear that the information you are requesting would be appropriate.

Please see FDA's guidance on Private Laboratories below.

https://www.fda.gov/downloads/ScienceResearch/FieldScience/UCM092191.pdf

Kind regards,

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

FDA U.S. FOOD & DRUG ADMINISTRATION

From: [redacted]
Sent: Friday, April 28, 2017 12:10 PM
To: OC GCP Questions
Subject: Clinical Trial question

Hello,

A research site would like to use our lab as a local lab for clinical trials. We would be placed on the FDA1572.

The research site does not want to give the lab any information. They are saying the information is confidential and we do not need it.

As a former Clinical Research Coordinator, we routinely gave our local lab a copy of the protocol, a schedule of the required draws with the dates to be drawn and a copy of the IRB approval letter.

I am searching for a document which clearly states what we as a local lab on the FDA1572 should receive from the research site.

I would appreciate any assistance you could provide.

Thank you in advance,