From: OC GCP Questions
To: [redacted].
Subject: Question for filling out the 1572
Date: Thursday, June 08, 2017 6:51:00 AM
Attachments: [redacted]

Good morning --

FDA's Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs - Frequently Asked Questions - Statement of Investigator (Form FDA 1572) found on FDA's web site at www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf . Specifically, Question 28 says:

28. What qualifies as a clinical laboratory facility for Section #4?

Section #4 is intended to identify clinical laboratories or testing facilities directly contributing to or supporting the clinical study [emphasis added] (for example, diagnostic labs performing blood work, imaging centers, cardiology labs, etc.). This may include analytical labs that provide pharmacokinetic analysis, and laboratories supplying efficacy data for clinical investigations conducted under an IND.

It sounds like your lab will be performing urine pregnancy tests, which are likely being done as part of the inclusion/exclusion criteria for a subject to qualify for entry into a study, and possibly being performed at other times during the conduct of the study. If that is the case, the results for the tests being performed by your lab are likely directly contributing to or supporting the clinical study, so the lab should be listed in box 4 of the 1572. However, I may not have all the pertinent information to make an accurate assessment, but you and the sponsor are in a better position to determine this based on a particular study.

However based on the information you provided in your email, it appears that the address does not have to be listed twice.

Again given that the Form FDA 1572 is collected and managed by the sponsor per 21 CFR 312.53(c), and serves as an agreement between the clinical investigator and sponsor, I recommend you further discuss this with your respective sponsor who may wish to reassess their position, or justify their position based on the FDA guidance.

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

U.S. FOOD & DRUG ADMINISTRATION

From: [redacted]
Sent: Wednesday, June 07, 2017 12:46 PM
To: OC GCP Questions

Subject: Question for filling out the 1572

To Whom it may concern,
I have a question regarding filling out the 1572. When filling out section #3 we fill in the site where the research is conducted. If we were to run a CLIA waived test let's say a urine pregnancy test is there any reason we needed to fill in Section #4 with the site address again. Our CLIA waived certificate has the site address. The test is a waived test per the Department of Health and Human Services and is not being run by an analytical lab. It seems the intent of Section #4 is for actual labs facilities to be listed. We do fill in the name and address of any analytical lab we use for all other tests that are run. I'd like to get an opinion if possible on not having to put the sites address in both section #3 and #4 if the tests are simply waived tests.
Regards,
[redacted]

[redacted]