From: OC GCP Questions
To: [redacted]
Subject: RE: Section 4 of Form FDA 1572
Date: Friday, July 08, 2016 4:02:00 PM
Attachments: [redacted]

Dear [redacted] -

Thank you for your question. It is difficult to comment on your question because the details of the study and the details of what the samples are for, and what the sponsor will be doing with the samples is not known.

However, as you already noted, FDA has guidance titled, "*Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs – Frequently Asked Questions – Statement of Investigator (Form FDA 1572)*" that states:

> V. SECTION #4: NAME AND ADDRESS OF CLINICAL LABORATORY FACILITIES TO BE USED IN THIS STUDY
>
> 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 (for example, diagnostic labs performing blood work, imaging centers, cardiology labs, etc.) [emphasis added]**. This may include analytical labs that provide pharmacokinetic analysis, and laboratories supplying efficacy data for clinical investigations conducted under an IND.

In general, if a laboratory or testing facility is performing procedures (e.g., analyzing specimens) as required by the study protocol, for example, to determine inclusion/exclusion of subjects, or for collection of significant endpoint safety or efficacy data, then it should be listed.

From a practical standpoint, if the facility where the samples are shipped is not analyzing the specimens for purposes of the study protocol, then this address may not need to be listed on the 1572. Nevertheless, this information should be referenced in the study records, so that the samples can be traced back through the chain of custody, if necessary.

The FDA Form 1572 is a form the sponsor is responsible for obtaining (refer to 21 CFR 312.53(c)). Since the 1572 is a sponsor document, I recommend that you discuss your question/concerns more thoroughly with them. I suggest you have others from your site involved in the discussion as well to make sure you are comfortable with the decision, since your investigator will be asked to sign the form and to comply with the investigational plan/protocol and pertinent regulations. If the sponsor would like to consult FDA about whether or not this lab should be included in box 4 of the 1572, they should contact the FDA review division they are working with.

I hope this information is useful. If you need further information and/or have additional questions, please feel free to contact us at the official GCP mailbox, gcp.questions@fda.hhs.gov. You may also find it useful to access the set of redacted GCP e-mails found at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGoodClinicalPractice/default.htm since we find that many questions and concerns are repeated over time.

Best Regards,

Janet

Janet Donnelly, RAC, CIP
Policy Analyst, Office of Good Clinical Practice
Office of Special Medical Programs, Food and Drug Administration

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From: [redacted]
Sent: Tuesday, July 05, 2016 12:25 PM
To: OC GCP Questions

Subject: Section 4 of Form FDA 1572

Good morning –

Based on the guidance/instructions *(below),* we have always listed all local and central laboratories in Section 4 of the Form FDA 1572. The information for central laboratories is provided by the Sponsor/CRO.

We have a study that does not reflect any laboratories on the 1572, but there are samples being sent to a laboratory. The Sponsor is stating that since they (the Sponsor) are doing all of the assessments/analytical work, there is no requirement to reflect the laboratory information on the 1572; <u>is this acceptable</u>?
The location for shipping the samples to the Sponsor is listed in the lab manual.

From the guidance/ instructions:

> ***FIELD 4: NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY***
> *Identify clinical laboratories or testing facilities directly contributing to or supporting the clinical study (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 Investigational New Drug Application (IND).*
>
> *If a laboratory is sending samples to satellite or other contract labs for additional testing, it is only necessary to list the primary laboratory, provided that laboratory can trace the samples to each of the satellite and/or contract labs where the tests were performed.*

Please clarify: If samples are being shipped to the Sponsor/Sponsor's lab for analyzing, does the lab need to be listed on the Form FDA 1572? The lab results from the analyses are not being sent back to us (the site).

Thank you, [redacted]

[redacted]