From: OC GCP Questions
To: [redacted]
Cc: [redacted]
Subject: RE: FDA form 1572
Date: Tuesday, March 21, 2017 2:23:00 PM
Attachments: [redacted]

[redacted]

As you already noted, the FDA guidance titled, "Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs – Frequently Asked Questions – Statement of Investigator (Form FDA 1572)" states that "Section #4 is intended to identify clinical laboratories or testing facilities directly contributing to or supporting the clinical study…" and "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."

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, we recommend that you discuss your question/concerns more thoroughly with them. We 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 helpful to you. Please contact us again at gcp.questions@fda.hhs.gov should you have additional GCP/HSP questions. 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.

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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: Thursday, March 16, 2017 6:14 PM
To: CDER DRUG INFO; OC GCP Questions
Cc: [redacted]
Subject: FDA form 1572

Hello,

I am trying to confirm if a central lab needs to be added to the FDA form 1572, and able to write in None/NA directly in line #4 on the form. According to the guidance on page 12 it states:

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.). This may include analytical labs that provide pharmacokinetic analysis, and laboratories supplying efficacy data for clinical investigations conducted under an IND. 29. If a laboratory is sending samples to satellite or other contract labs for additional testing, should these labs be identified in Section #4? 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.

The sponsor is saying that since the lab does not provide results to our site they want to leave this off the form, will you confirm if this is acceptable?

[redacted]

[redacted]