From: OC GCP Questions
To: [redacted]
Subject: Form FDA 1572
Date: Thursday, April 27, 2017 6:18:00 AM
Attachments: [redacted]

Good morning –

FDA's 1572 guidance https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf states --

V. SECTION #4: NAME AND ADDRESS OF CLINICAL LABORATORY FACILITIES TO BE USED IN THIS STUDY (page 12)

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.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
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From: [redacted]
Sent: Wednesday, April 26, 2017 6:40 PM
To: OC GCP Questions
Cc: [redacted]
Subject: Form FDA 1572

Hello,

Thank you in advance for your guidance.

We have a question that relates to Section ***4. NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY*** on the Form FDA 1572.

Our interpretation is that the labs listed in this section are only those labs that will assess specimens that will make determinations on the care of and treatment of the subjects participating in the trial, as well as assessing for adverse events.

We have always understood that if a specimen or test is being done that will not impact the study subject (ie: DNA testing or assays that are assessed after the subject's study participation solely for research and have nothing to do

with subject care or safety) then a central laboratory used for processing this type specimen/test are not required to be listed on the 1572.

Could you please clarify. Our understanding is laboratories listed on the 1572 are those that impact subject care. Research labs that will not impact the care provided directly to the study participate are not listed on the 1572.

Kindest regards,

[redacted]

[redacted]