From: OC GCP Questions
To: [redacted]
Subject: 1572 question-adding central labs/imaging vendor
Date: Thursday, April 20, 2017 11:04:00 AM
Attachments: [redacted]

Good morning –

FDA's 1572 guidance might be helpful to you

https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf 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.

From the limited information in your email, it appears that the central imaging vendor may need to be listed in section 4.

I hope this information was helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

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

From: [redacted]
Sent: Thursday, April 20, 2017 10:26 AM
To: OC GCP Questions
Subject: 1572 question-adding central labs/imaging vendor

Hello,
Would you recommend that investigator sites add a central imaging vendor to Box 6 of the 1572? The only interaction with the vendor would be the compilation and submission of tumor images to them.
Thank you.

[redacted]