From: OC GCP Questions
To: [redacted]
Subject: GCP Question/Guidelines
Date: Friday, February 15, 2019 12:38:53 PM
Attachments: [redacted]

Good afternoon –

While “Central Readers” is not specifically defined in FDA regulations. Please see FDA’s guidance on the 1572 form. https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf

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.). This may include analytical labs that provide pharmacokinetic analysis, and laboratories supplying efficacy data for clinical investigations conducted under an IND.

Please note while an FDA form, the 1572 is meant to provide the study sponsor with complete information regarding the study at a given site. In addition, once signed, it is an agreement by the CI that he/she will be compliant with the investigational plan and applicable regulations. Since much of the information on this form is required in an IND application, most sponsors do submit copies of their 1572s to FDA, but it is not required.

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

Kind regards,

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From: [redacted]
Sent: Thursday, February 14, 2019 2:41 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: GCP Question/Guidelines

Are there Guidances on Central Readers for a trial?
Thanks!