

From: OC GCP Questions
To: [REDACTED]
Subject: FDA 1572 Section 4 completion guidance
Date: Wednesday, June 07, 2017 9:13:00 AM
Attachments: [REDACTED]

Good morning –

Based on the limited information in your email, it appears that both the MRI and reading center should be listed in Section 4. I cannot tell if you are the sponsor. The 1572 is a sponsor required form. If you are not the sponsor, please also consult your sponsor for advice.

Kind regards,

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From: [REDACTED]
Sent: Tuesday, June 06, 2017 9:39 AM
To: OC GCP Questions
Subject: FDA 1572 Section 4 completion guidance

Hello,

Would you be so kind as to settle a discussion regarding whether MRI facilities should be listed on Section 4 or Section 3 of the FDA 1572?

We are conducting a study in which the subject will have MRI performed to assess clinical outcomes based on MRI derived parameters and measure secondary endpoints of the study.

MRI will be performed by an local MRI facility and then will be sent to centralizer reading center for efficacy time points. All MRI Scans will also be reviewed locally for safety.

The FDA guidance states that imaging centers are included in Section 4.

"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.”

However my colleague is determined that the local MRI center should be listed in Section 3 and the Central Reader listed under Section 4.

The rationale is based on the below statement.

26. What qualifies as a research facility for Section #3?

Section #3 is intended to identify facilities where study activities will be conducted and clinical data will be generated or collected. This includes facilities where subjects will be seen and study procedures performed. For example, this might include locations such as health care facilities where the test article will be administered, or where physical exams will be performed. Facilities where other important clinical investigation functions are performed may also be identified in Section #3. For example, a research laboratory where the test article is prepared, a special storage facility where the test article will be kept, or a location where tissue specimens are collected should be listed in this section.

Should we list both the local MRI center and reading center under Section 4?
Or should the local MRI center be listed on section 3 and the Central reader listed under Section 4?
Thank you in advance for your response.

Kind regards,

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