

From: OC GCP Questions
To: [REDACTED]
Subject: 1572 Statement of Investigator, Item 4 Question
Date: Friday, June 02, 2017 10:41:00 AM
Attachments: [REDACTED]

Good morning --

Please see FDA's guidance document below. It might be helpful for you to review it.

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

Although not defined in the guidance, generally, imaging centers would those centers that perform scans – CT scans, MRIs etc. Since the 1572 is a sponsor form, the sponsor should be able to assist you in determining what should be listed in section 4.

Kind regards,

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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, June 01, 2017 4:09 PM
To: OC GCP Questions
Subject: 1572 Statement of Investigator, Item 4 Question

Hello,

I am wondering what is considered an "imaging center" listed under Item 4 of the Statement of Investigator 1572 form. Could someone please provide some guidance?

Kind Regards,

[REDACTED]

[REDACTED]