

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: Guidance for Line 4 of 1572
Date: Thursday, September 24, 2015 1:50:27 PM

Good afternoon –

Based on the information in your email and FDA's 1572 guidance document (below), it appears that the X-Ray vendor does not need to be listed on the 1572 form.

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

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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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, September 24, 2015 1:29 PM
To: OC GCP Questions
Subject: Guidance for Line 4 of 1572

We are seeking guidance on whether an imaging center utilized for a clinical trial should be listed on the 1572. We will be conducting a study that requires an x-ray be performed as part of the screening procedures unless a subject can provide an x-ray performed in the past 12 months. This is a one time standard of care procedure that has no study specific parameters outside of it being performed. If the subject can not provide results of an x-ray performed previously, we have an established vendor who will perform the procedure during the screening period. Does this facility need to be listed on line 4 of the 1572?

Thank you,

[REDACTED]