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,

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

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]