From: OC GCP Questions
To: [redacted]
Subject: FDA 1572 Inquiry
Date: Friday, August 23, 2019 11:40:16 AM
Attachments: [redacted]

Good morning –

Even though the images are for standard care, they are also being used for the research study, so it would appear that the imaging center should be listed on the 1572 form.

The 1572 form is a sponsor form. Therefore, if you are not the sponsor of the clinical study, it best to ask the sponsor. Additionally, the sponsor can also confer with the FDA reviewing division that is overseeing the IND.

Kind regards,

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

From: [redacted]
Sent: Thursday, August 22, 2019 6:15 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: FDA 1572 Inquiry

Hello,

Per the attached guidance, defines Section #4 of the 1572 as 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.). If there was a facility where imaging was being completed as a standard of care and not done for research purposes (the images would have been done whether or not the patient was involved in a clinical trial, but the images would be used for research purposes), would the FDA consider that facility as needing to be added to Section #4?

Thank you,
[redacted]