

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: Form FDA 1572 Box 4
Date: Friday, August 30, 2019 11:08:16 AM
Attachments: [REDACTED]

Good morning –

Thank you for your email. Please see FDA's Guidance on the 1572 Form.
<https://www.fda.gov/media/78830/download>

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.

Based on the guidance, it appears the imaging center should be listed on the 1572 form. Remember that the form is a sponsor form. Therefore you should seek advice from the sponsor.

Kind regards,

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



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, August 29, 2019 2:49 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Cc: [REDACTED]
Subject: Form FDA 1572 Box 4

Thank you for providing this forum as a resource for GCP queries.

As a dermatology research facility, our protocols regularly involve photography as a primary or secondary endpoint.

Most sponsors utilize a vendor [REDACTED] to provide the equipment and manage the transfer and analysis of the images.

The majority of sponsors automatically include the photography vendor in Box 4 of the 1572; however, it is not always included. As a site, we are hesitant to submit a 1572 without it listed.

Would you please clarify or confirm whether, under these circumstances, the photography vendor should be included?

Kind Regards,

