

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: FDA 1572 question
Date: Friday, November 15, 2019 9:57:00 AM
Attachments: [REDACTED]

Good morning –

Thank you for your email. We are frequently asked about completing the Form FDA 1572, and it's a question for which there is not always a straightforward answer. Many people do not realize that one of the main purposes of the 1572 is to provide the sponsor with advance information about the clinical site(s) where the research will take place, the investigator's qualifications, and information about other facilities that will be performing protocol required tests. Providing this information to the sponsor allows the sponsor to establish and document that the investigator and site are qualified to conduct the study. The other main purpose of completing the 1572 is to obtain the investigator's commitment to comply with FDA's regulations for conducting the clinical investigation.

Block #4 on the 1572 asks the clinical investigator to identify laboratories or testing facilities directly contributing to or supporting the clinical trial (for example, diagnostic labs performing blood work, imaging centers, cardiology labs, etc.). In general, if a laboratory or testing facility is performing procedures (e.g., analyzing specimens) as required by the study protocol or for collection of significant endpoint safety or efficacy data, then it should be listed.

You will have to decide or ask the sponsor since the 1572 form is a sponsor form. In general, local labs are not listed on the 1572 form.

It might be helpful for you to review FDA's 1572 Form guidance.
<https://www.fda.gov/media/78830/download>

Kind regards,

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



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From: [REDACTED]
Sent: Thursday, November 14, 2019 12:01 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: FDA 1572 question

Hello,

I am hoping someone may be able to provide some guidance on section#4 of the 1572.

If a patient is using a local lab at a hospital near their home for SOC labs that determine whether or not patient can treat bc the main facility is hours from their home is that lab required to be listed on the 1572?

