

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: question regarding Section 4 of Form FDA 1572
Date: Thursday, October 30, 2014 12:46:55 PM

Good afternoon –

FDA's 1572 guidance
(<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf>) states --

V. SECTION #4: NAME AND ADDRESS OF CLINICAL LABORATORY FACILITIES TO BE USED IN THIS STUDY

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.

29. If a laboratory is sending samples to satellite or other contract labs for additional testing, should these labs be identified in Section #4?

It is only necessary to list the primary laboratory, provided that laboratory can trace the samples to each of the satellite and/or contract labs where the tests were performed.

It appears from the limited information in your email that the lab you describe may not need to be placed on the 1572 form.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional information.

Kind regards,

Doreen M. Kezer, MSN
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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: Wednesday, October 29, 2014 1:06 PM
To: OC GCP Questions
Subject: question regarding Section 4 of Form FDA 1572

Hello –

I have a question regarding what labs need to be included (or not) in section #4 of the Form FDA

