

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: A question regarding 1572 laboratory section
Date: Thursday, June 11, 2015 11:43:21 AM

Good morning –

Please see the FDA guidance (link below) on the 1572 form. Based on the information in your email, it appears that only the primary labs need to be listed on the 1572 as the laboratory can trace the samples to each satellite and/or contract lab.

<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf>

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.

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
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Office of Good Clinical Practice
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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, June 10, 2015 10:12 AM
To: OC GCP Questions
Cc: [REDACTED]
Subject: A question regarding 1572 laboratory section

Hi,

I have questions about listing labs on the 1572 and am hoping you can please advise.

For a multicenter study, sites use primary labs (internal and external). In addition, some testing is

done by a project's central labs. Primary labs are listed on 1572. If the primary labs have a subcontract with a secondary lab to do tests that the primary lab cannot do, should that subcontracted lab be listed?

A project's central labs which are in different states run tests for endpoints, eligibility, etc. Should each site list the project's central lab to cover all of these, or should they list each individual lab under the central lab? The central lab also has a subcontract with a lab outside of the U.S. to run a test on the investigational product. Should this lab be listed on each site's 1572?

Thanks in advance for any advice you can provide!

[REDACTED]