

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: 1572 inclusion questions
Date: Wednesday, August 13, 2014 11:36:38 AM

Good morning –

Based on the scenarios you describe in your email, I don't think the satellite labs or the CT scanning facilities need to be listed on the 1572 as both appear to be associated to a facility that is currently listed on the 1572.

For more information on FDA's 1572 form, please see the guidance link below. It might be helpful for you to review this guidance.

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

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,

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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: Tuesday, August 12, 2014 3:52 PM
To: OC GCP Questions
Subject: 1572 inclusion questions

Dear Colleagues:

We would be most grateful if you would please give us your best advice based on the questions and scenarios as described below.

#1: Does each satellite lab a patient may utilize need to be included on the 1572, if all specimens will be processed at the central facility.

Example: Long distance patient would like to complete safety bloodwork at a [redacted] facility close to home). [redacted] is also the lab of record for the main clinical trial centre and all blood specimens for Labcore are will be centrally regardless of where they are obtain.

#2: Does the local CT scan facility need to be included on the 1572?

Example: In the [redacted], we have a request to allow long distance patients participating on a non-small cell lung cancer trial and who are off treatment drug, to complete CT scans closer to home to assess progression-free survival provided that the local scan is compatible with the main clinical trial centre scan. The local scan will be sent to the main clinical trial centre listed on the 1572 for [redacted] assessment.

Many thanks for your help in advance

Kind regards

[redacted]