From: OC GCP Questions
To: [redacted]
Subject: FDA 1572 question - Change to central lab information
Date: Thursday, February 21, 2019 9:03:16 AM
Attachments: [redacted]

Good morning –

No update by CI is needed for the reason you state. Please see FDA's 1572 guidance.

https://www.fda.gov/downloads/regulatoryinformation/guidances/ucm214282.pdf It states -

7. When must a 1572 be updated or a new 1572 completed and signed by an investigator to reflect new or changed information?

There are two instances when it is necessary for an investigator to complete and sign a new 1572: when an investigator is participating in a new protocol that has been added to the IND and when a new investigator is added to the study (21 CFR 312.53(c)).

If there are other changes to information contained on a signed and dated 1572 (e.g., an IRB address change, the addition of new subinvestigators, the addition of a clinical research lab), the investigator should document the changes in the clinical study records and inform the sponsor of these changes, so that the sponsor can appropriately update the IND. The 1572 itself does not need to be revised and a new 1572 need not be completed and signed by the investigator. The sponsor can accumulate certain changes and submit this information to the IND in, for example, an information amendment or a protocol amendment.

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
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Wednesday, February 20, 2019 6:46 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: FDA 1572 question - Change to central lab information

Good evening,

I wanted to reach out to determine if investigators are required to complete a new FDA 1572 form for the following:

- changes to the central lab address on the FDA 1572 (i.e. the lab moved)

Any guidance you can provide is greatly apprecaited.

Please reply all to ensure timely response(s) from Pharm-Olam team.

Upcoming absences: None.

[redacted]

[redacted]