From: OC GCP Questions
To: [redacted]
Subject: RE: 1572 question
Date: Tuesday, March 26, 2019 11:53:00 AM
Attachments: [redacted]

Dear [redacted] -

Thank you for your question. FDA has guidance titled, "*Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs – Frequently Asked Questions – Statement of Investigator (Form FDA 1572*) (see https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf). Question #7 in this guidance document addresses when a 1572 must be updated or a new 1572 must be completed and signed by the investigator. The guidance says:

> ***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.

According to this FDA guidance, you do not need to revise the 1572 form to add a clinical lab, however, the investigator should document the change in the study records, and inform the sponsor of the change. Given that the 1572 is a sponsor form, the sponsor may have specific expectations or instructions to provide you.

I hope this information is useful. If you need further information and/or have additional questions, please feel free to contact us at the official GCP mailbox, gcp.questions@fda.hhs.gov. You may also find it useful to access the set of redacted GCP e-mails found at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGoodClinicalPractice/default.htm since we find that many questions and concerns are repeated over time.

Best Regards,

Janet
Janet Donnelly, RAC
Policy Analyst

Office of the Commissioner
Office of Good Clinical Practice
U.S. Food and Drug Administration

From: [redacted]
Sent: Thursday, March 21, 2019 2:08 PM

To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: 1572 question

Hello,
I have a question concerning if I need to feel out a new 1572 for our study. We are adding a new clinical lab to our study, to help process blood samples collected from subjects. Can this addition be stated in amendment?
Thank you,

[redacted]

[redacted]