From: OC GCP Questions
To: [redacted]
Subject: Updated PI information
Date: Tuesday, October 10, 2017 11:36:57 AM
Attachments: [redacted]

Good morning –

Please see FDA's guidance on the 1572 form.
https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf

It states --

6. Does the 1572 need to be submitted to FDA?

No. Although the sponsor is required to collect the 1572 from the investigator, FDA does not require the form to be submitted to the agency. Many sponsors submit the 1572 to FDA, however, because it collects, in one place, information that must be submitted to FDA under 21 CFR 312.23(a)(6)(iii)(b).

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.

There is no requirement that the updated 1572 be submitted to FDA within 30 days.

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: Monday, October 09, 2017 8:41 PM
To: OC GCP Questions
Subject: Updated PI information

Hello,

I have a question regarding the timeframe to have an updated 1572 for PI information submitted, does the sponsor need to submit the updated 1572 within 30 days of received from investigator?

Thank you,

[redacted]