From: OC GCP Questions
To: [redacted]
Subject: Sub-Investigator 1572 Updates
Date: Tuesday, September 17, 2019 11:31:18 AM
Attachments: [redacted]

Good morning –

Please see FDA 1572 Form guidance https://www.fda.gov/media/78830/download 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.

There is no time frame mentioned as to when an information amendment or a protocol amendment needs to be sent to FDA. This would be up to the sponsor.

Kind regards,

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From: [redacted]
Sent: Monday, September 16, 2019 4:17 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Sub-Investigator 1572 Updates

Hello,

If a new subinvestigator is being added to a study and seeing patients as part of that study, does a new 1572 need to be completed and signed by the investigator prior to them participating in the

research? And if not, is there a specific timeline by which they will need to be added to the 1572 (e.g 1 week after seeing a patient, 1 month after, 3 months after)?

Thanks!

[redacted]