From: OC GCP Questions
To: [redacted]
Subject: Update FDA 1572
Date: Tuesday, July 02, 2019 10:04:28 AM
Attachments: [redacted]

Good morning –

Please see FDA's Form 1572 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.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

FDA U.S. FOOD & DRUG ADMINISTRATION

From: [redacted]
Sent: Tuesday, July 02, 2019 8:37 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Update FDA 1572

Dear ALL,

I allow me to contact you because I would like to know if it is compulsory to update FDA 1572 during study. I have initial FDA 1572 but I have a new Sub Investigator

Thank you for your help

Kind regards

[redacted]