From: OC GCP Questions
To: [redacted]
Subject: Removing a Sub-I from 1572
Date: Tuesday, December 17, 2019 10:49:06 AM
Attachments: [redacted]

Good morning –

Please see the guidance that you reference. https://www.fda.gov/media/78830/download Yes you are correct, the site does not need to update the 1572 form. The 1572 form is a sponsor form and is updated by the sponsor when necessary as outlined in question 7 of the guidance, including removing a Sub-I from the clinical investigation. 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

From: [redacted]
Sent: Tuesday, December 17, 2019 10:18 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Removing a Sub-I from 1572

Hello,

We had a question from one of our colleagues that we hope you can help with regarding changes to Sub-Investigators. If a sub-investigator leaves a site or chooses to no longer participate on a trial, based on the guidance (FAQs – Statement of Investigator (Form FDA 1572) – FAQ #7), the investigational site is not required to update the 1572 but should notify the sponsor. The FAQs further discusses that the sponsor should notify the FDA in case of adding a sub-investigator via updating the IND but does not directly speak to removing a sub-investigator. Should the sponsor also update the IND in the case of removing a sub-investigator? If so, what is an appropriate time frame for updating given the flexibility to "accumulate" such changes to report multiple updates at once? If not, what process should be followed? Please let us know. Thanks!