From: OC GCP Questions
To: [redacted]
Subject: Sub-investigators listed on the FDA1572
Date: Friday, August 16, 2019 1:13:10 PM
Attachments: [redacted]

Good afternoon –

Please see the email from the Center for Drugs (CDER) for your 1572 question. You can remove the sub-investigator from the site but the information can be send in an update to the IND.

For the FD follow-up question –

Financial disclosure forms and individuals who leave a site during the conduct of a study.

FDA has regulations concerning financial disclosure in Part 54 of Title 21 of the Code of Federal Regulations (CFR). Specifically, Certification and Disclosure Requirements are outlined under 21 CFR 54.4 (b), which states:

"The clinical investigator shall provide to the sponsor of the covered study sufficient accurate financial information to allow the sponsor to submit complete and accurate certification or disclosure statements as required in paragraph (a) of this section. The investigator shall promptly update this information if any relevant changes occur in the course of the investigation or for 1 year following completion of the study."

Collecting an updated financial disclosure form outlining any reportable interests from an individual at the time that they leave a study would be in accordance with the above financial disclosure regulation.

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: CDER DRUG INFO
Sent: Friday, August 16, 2019 11:53 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: RE: Sub-investigators listed on the FDA1572

Hello,

The answer is:

Yes, when *a few months later there is a major change and the 1572 is updated, the sub-investigator that left should be removed. The information should also be submitted to the IND with this update if appropriate or with the next progress report such as an information amendment or a protocol amendment.*

Hope that helps. Have a great weekend Doreen!

Holli Tierno
Pharmacist | Division of Drug Information
Druginfo@fda.hhs.gov | CDERSBIA@fda.hhs.gov | AskGDUFA@fda.hhs.gov

From: OC GCP Questions
Sent: Friday, August 16, 2019 11:31 AM
To: CDER DRUG INFO <DRUGINFO@fda.hhs.gov>
Subject: Sub-investigators listed on the FDA1572

DDI –

Can you comment on the 1572 query? Am I correct? I will handle the FD question. Thanks Doreen

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From: [redacted]
Sent: Friday, August 16, 2019 4:20 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Cc: CDER DRUG INFO <DRUGINFO@fda.hhs.gov>
Subject: RE: Sub-investigators listed on the FDA1572

Thank you for the information Doreen. Please see additional questions below in red.

Kind Regards,

[redacted]

[redacted]

[redacted]

Subject: Sub-investigators listed on the FDA1572

Good afternoon –

Thank you for your email. So, I think the 1572 Form guidance (link below) does answer your first question.
https://www.fda.gov/media/78830/download

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.
The above confirms that when a sub-investigator leaves the site the 1572 does not have to be updated. This however does not answer my question. Which is, if a sub-I leaves the site the 1572 is not updated, but say for example a few months later there is a major change and the 1572 is updated, should the sub-I that left be removed at this stage?

I believe the sponsor can informed FDA that the sub-investigator left the study in an information amendment or a protocol amendment.

Please see FDA's Financial Disclosure Guidance. https://www.fda.gov/media/85293/download

Clinical investigators are included in the definition even if they did not participate for the entire length of the study. If a clinical investigator did not participate in the entire study,
information collected should be for the period of time he or she participated in the study and for one year following the end of his or her participation. Yes, but should the sub-investigator sign another Financial Disclosure form when the leave the company?

I have copied CDER Drugs in case they have additional information to add.

Kind regards,

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

From: [redacted]
Sent: Thursday, August 15, 2019 5:44 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>; CDER DRUG INFO <DRUGINFO@fda.hhs.gov>
Subject: Sub-investigators listed on the FDA1572

Dear FDA communication,

Could you please confirm if a sub-investigator no longer works for a clinical research site, should his/her name be removed from an updated FDA1572 or remain on the form even though they are no longer working for the company? I read through the FDA FAQ guidelines, but cannot find a definite answer.

In addition to the above, if no changes to a sub-investigators financial interest during the study, should they sign a financial disclosure form when they resign from the company or at the end of the trial? Lately more monitors are asking for these end of trial FD's even if no changes occurred during the study.

Please let me know if you require any additional informantion.

[redacted]