From: OC GCP Questions
To: [redacted].
Subject: RE: FDA 1572 hand written correctons
Date: Tuesday, October 18, 2016 1:05:20 PM

Hi [redacted],

Please see the highlighted section in my original answer. Corrections do not need to be made to the form. The changes should be documented in the study records and submitted to the sponsor. The 1572 is an agreement between the sponsor and clinical investigator, so you may also wish to contact the sponsor of the study to confirm how they would like to be apprised of this change.

Sincerely,
Bridget A. Foltz, MS, MT(ASCP)
Policy Analyst, Office of Good Clinical Practice
Office of the Commissioner, Food and Drug Administration

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: [redacted]
Sent: Tuesday, October 18, 2016 12:16 PM
To: OC GCP Questions
Subject: RE: FDA 1572 hand written correctons

Hello Bridget,

Thank you for the follow up. I understand the instances when a new 1572 needs to be generated but if the study sponsor requires minor changes (as below or corrections of typographical errors), is it acceptable to make hand written changes?

Kind Regards,

[redacted]

[redacted]

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From: OC GCP Questions [mailto:gcp.questions@fda.hhs.gov]
Sent: Tuesday, October 18, 2016 12:07 PM
To: [redacted]
Subject: RE: FDA 1572 hand written correctons

Hello [redacted]

Your question is addressed in the FAQ Guidance on Statement of Investigator (Form FDA 1572) - http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf :

Section I
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.

I hope that this information is helpful. Please contact us at gcp.questions@fda.hhs.gov if you have further questions.

Sincerely,
Bridget A. Foltz, MS, MT(ASCP)
Policy Analyst, Office of Good Clinical Practice
Office of the Commissioner, Food and Drug Administration
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From: [redacted]
Sent: Monday, October 17, 2016 4:15 PM
To: OC GCP Questions
Subject: FDA 1572 hand written correctons

Hello,

One of our sub investigators listed on the 1572 for a study did not participate in study conduct and we would like to update the form by lining through the name and have the PI sign and date the correction-can you please let me know if handwritten corrections to the form is acceptable?

Thank you,

[redacted]

[redacted]

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