From: OC GCP Questions
To: [redacted]
Subject: FDA Form 1572 Question
Date: Wednesday, September 24, 2014 12:56:50 PM

Good afternoon -

Replacement of the original signed 1572 need not be revised unless a different clinical investigator is to take over the site, which would require a new commitment to the study via his/her signature on a new form. The study sponsor should be advised of any other changes to the information captured on the form that occur during the course of the study and the sponsor will update FDA in their next progress report for the study.

Please see the guidance document on FDA's 1572 form.
http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf 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.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

Doreen M. Kezer, MSN
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Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Tuesday, September 23, 2014 9:38 AM
To: OC GCP Questions
Subject: FDA Form 1572 Question

Good Day. If a sub-investigator (who is a SC) is no longer participating on a clinical trial and they are noted on the FDA Form 1572, how soon is the site required to remove the sub-investigator from the FDA Form 1572 and update the FDA Form 1572?

Thanks,
[redacted]