From: OC GCP Questions
To: [redacted]
Subject: Question regarding Form 1572
Date: Wednesday, September 02, 2015 9:08:25 AM

Good morning –

The FDA 1572 form guidance http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf 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.

Based on the information in your email, the 1572 does not need to be signed by the investigator especially since the study was closed out in 2014.

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
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

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, September 01, 2015 2:27 PM
To: OC GCP Questions
Cc: [redacted]
Subject: Question regarding Form 1572

I am the regulatory coordinator for a study site. A sponsor is asking me to complete an FDA form 1572 for a study that we closed-out in October of 2014. The sponsor is indicating that they had an update to the laboratory section of the 1572 sometime during the study, and that sites "missed it" when the sponsor sent it. According to the sponsor, this is just now being discovered. They are asking that I complete this 1572 and have the PI sign it now. I'm unsure if I should do this as the study is closed, and subsequently the delegation of authority log has end dates for the involvement of all persons that were on the FDA form 1572. Therefore if the PI signs and dates it now, it would look like those people that involvement has ended for are involved again. Any guidance would be appreciated in this matter.

Thank you,
[redacted]