From: OC GCP Questions
To: [redacted]
Subject: 1572 Update Question
Date: Friday, January 30, 2015 1:17:47 PM

Good afternoon –

Based on the information you provided, the 1572 form does not need to be updated. As stated in the guidance, the sponsor can accumulate certain changes and submit this information to the IND in, for example, an information amendment or a protocol amendment.

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

From: [redacted]
Sent: Thursday, January 29, 2015 1:54 PM
To: OC GCP Questions
Cc: [redacted]
Subject: 1572 Update Question

Dear Sir or Madam,

I have a question about updating a 1572. In the FAQ – Statement of Investigator, Section 7 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.

We have had a protocol title change and we have a site who is refusing to update their 1572 because the change does not include a new investigator. I would like to know, in the case of a

protocol title change would the 1572 need to be updated to reflect this change in box 7?

Thank you,
[redacted]