From: OC GCP Questions
To: [redacted]
Subject: Updated 1572 required
Date: Thursday, November 20, 2014 2:58:49 PM

Good afternoon –

Based on the information in your email, it appears the 1572 does not need to be updated. The FDA 1572 guidance states- http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf

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

From: [redacted]
Sent: Wednesday, November 19, 2014 7:38 PM
To: OC GCP Questions
Subject: Updated 1572 required

Hello,

My company is asking sites who are participating in our clinical trial, to update the 1572 based on the new version that came out, that expires Apr 2015. We are asking the sites to update the 1572 to check section 8 for Phase 2 or 3. Our study is a phase 4. The sites have not previously checked that box because it is indicated in another section that the study is a phase 4. I am asking because we have sites refusing to update the 1572 as they state it is not required. If you could please let me know if

this is a requirement of the FDA or seems to be just a requirement of the CRO, I would appreciate it so I know how to address the PIs/Sites that are refusing to update.

Thank you,
[redacted]