From: OC GCP Questions
To: [redacted]
Subject: IRB Address Change
Date: Tuesday, July 07, 2015 2:52:31 PM

Good afternoon –

The FDA guidance document for the 1572 form
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.*

It is not necessary to update the 1572 form when an IRB address changes.

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, July 07, 2015 10:00 AM
To: OC GCP Questions
Subject: IRB Address Change

Greetings,

[Redacted] has relocated and we have already updated our FDA registration. We have investigative sites that are asking about updating the address on the form 1572. I believe since the actual IRB is not changing that it would not be necessary for them to update/resubmit the 1572. Please advise.

Thank you in advance,

[redacted]