From: OC GCP Questions
To: [redacted]
Subject: FDA1572 / Change of Address of Principal Investigator
Date: Friday, September 30, 2016 2:32:00 PM

Good afternoon –

You are correct, per FDA's 1572 guidance question #7a new 1572 is not required.
http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf

You should inform the reviewing IRB of the change of address. Also it might be good to inform the regulatory project manager at FDA as well but an updated 1572 is not needed. The sponsor can submit this information to the IND in an information amendment or a protocol amendment. Of course the subjects would need to be informed as well.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Thursday, September 29, 2016 7:49 PM
To: OC GCP Questions; CDER DRUG INFO
Subject: FDA1572 / Change of Address of Principal Investigator

Good evening,

I would like to inquire about a question that came up for one of our US sites who will be moving next month.

Although Item No 7 seems to imply that a site's change of address does not grant a FDA1572 revision, we would like to make sure this is well the case.

If it is needed, what kind of consideration should be given to the timing of PI's signature vs date when study subjects will be seen at the new address? Is there any problem with a PI signature a few days prior to or after the effective date or it needs to be the exact same date?

Thanking you in advance for your time and assistance.

Best regards,
[redacted]

[redacted]