From: OC GCP Questions
To: [redacted]
Subject: 1572 Box 3 and Suite #s
Date: Thursday, September 25, 2014 12:50:35 PM

Good afternoon –

The only time that the 1572 form needs to be updated immediately is when a new clinical investigator takes over the study. Also, you only need to list the main address on the 1572. Please see the guidance document below

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.

20. What address should be entered into Section #1?
The address where the investigator can be reached by mail or in person should be entered in Section #1 of the 1572. Usually, this corresponds to the investigator's work or business address.

Again, replacement of the original signed 1572 need not be revised unless a different clinical investigator is to take over the site, which would require a new commitment to the study via his/her signature on a new form. The study sponsor should be advised of any other changes to the information captured on the form that occur during the course of the study and the sponsor will update FDA in their next progress report for the study.

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: Wednesday, September 24, 2014 5:58 PM
To: OC GCP Questions
Subject: 1572 Box 3 and Suite #s

Question on appropriate way to complete 1572 when multiple suites involved.

When we first started in research, we had one suite within our building. We have now expanded to 4 suites on 3 different floors—these suites are all under the same company umbrella. Mail is addressed to our main suite and this is listed in box 1 of the 1572 as the main address, the location to where drug should be shipped and all correspondence should come. We are unsure whether to update the process for completing the 1572.

Is it acceptable to remove the suite numbers from Box 3? Alternatively, should each suite number be listed as a separate location or all suite numbers on one location?

Thank you for your assistance.

[redacted]