

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: 1572
Date: Friday, October 17, 2014 11:48:49 AM

Good morning --

<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf>

The above guidance link would be helpful to you. Question 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.

I assume the sponsor is aware of the change of address of your research site.

The continuation pages appear at the **end** of the document not on top of the page you are working on. If you continue to have problems with the form you can email your questions to CDER Forms office at ESUB@fda.hhs.gov

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

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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: Thursday, October 16, 2014 12:36 PM
To: OC GCP Questions
Subject: 1572

To whom it may concern,

I am the new research coordinator for [redacted].

We have recently moved to a new location and I would like to change the address on the 1572.

Would it be possible to have someone help me with this?

Does it need to be done online now?

When I tried to complete this form, I found that the continuation pages for additional labs would not load.

Thanks you,
[redacted]