

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: Clinical Research Site
Date: Thursday, June 13, 2019 11:06:33 AM
Importance: [REDACTED]

Good morning –

Please see FDA's 1572 Q/A. <https://www.fda.gov/media/78830/download> It 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 don't understand your second question. Sorry. If the question involves your institution, you will have to follow your institutional policies and procedures.

Kind regards,

Doreen M. Kezer, MSN

Senior Health Policy Analyst

Office of Good Clinical Practice

Office of the Commissioner, FDA

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From: [REDACTED]
Sent: Thursday, June 13, 2019 10:15 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Clinical Research Site
Importance: High

Good Morning we need guidance as we have received conflicting information from different sponsors.

We are going to move our site and there are several active studies:

We are of the opinion that new FDA1572 will need to be submitted and some sponsors say that a new address is not a trigger for a new 1572 and we do not agree, kindly clarify .

We are self- identified [REDACTED] do we need to inform the department in writing and if so where or by email of the new address.

Thank you !

