From: OC GCP Questions
To: [redacted]
Cc: CDER DRUG INFO
Subject: Change of name of business/ entity
Date: Monday, November 04, 2019 11:36:52 AM
Attachments: [redacted]

Good morning –

Please see FDA's guidance on the 1572 form 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.

Kind regards,

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From: [redacted]
Sent: Friday, November 01, 2019 6:32 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>; CDER DRUG INFO <DRUGINFO@fda.hhs.gov>
Subject: Change of name of business/ entity

Hello,

We recently successfully formed a new entity and have changed our organization's name. The address and team members in respective addresses/ site have not change.

Are sites required to change update all our 1572s of all currently opened studies to reflect the change of name?

I appreciate your assistance on this. I would like to this information prior to making changes.

Thank you.

Kindly,