

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: Question about 1572 Form and the updates requirements
Date: Friday, August 23, 2019 11:35:28 AM
Importance: High

Good morning –

The FDA 1572 guidance <https://www.fda.gov/media/78830/download> also states --

16. Should a new form be prepared and signed when the OMB expiration date is reached?

No. There is no need to prepare and sign a new 1572 when the OMB expiration date has been reached.

There is no need to update the form based solely on the expiration date.

Kind regards,

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From: [REDACTED]
Sent: Thursday, August 22, 2019 3:01 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Question about 1572 Form and the updates requirements
Importance: High

To whom it may concern,

I am contacting you since we have an internal discussion regarding the requirements in order to complete a new 1572 form in IND study.

According to FDA guideline topic 7, 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.

However some FDA inspectors have been requested to update the form every time that the expiration date change.

Could you please confirm the correct implementation?

Thank you so much in advance

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]