

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: Expired FDA 1572 used after new FDA form released
Date: Tuesday, June 04, 2019 10:23:54 AM
Attachments: [REDACTED]

Good morning -

Please see the 1572 guidance below.

<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.

If a 1572 form needs to be updated, as stated above, the 2022 expired date 1572 form should be used. Also, if a new form is to be completed for a new study, the 2022 form should be used.

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: Monday, June 03, 2019 11:00 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Cc: [REDACTED]
Subject: Expired FDA 1572 used after new FDA form released

To Whom it May concern:

Can sites still utilize the FDA 1572 (expired 28-Feb-2019) even after the FDA has released the new form with an updated expiration date (31-Mar-2022)?

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]