

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: Updated 1572 OMB Expiration Date March 31, 2022
Date: Tuesday, May 07, 2019 12:59:07 PM
Attachments: [REDACTED]

Good afternoon –

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?

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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.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA



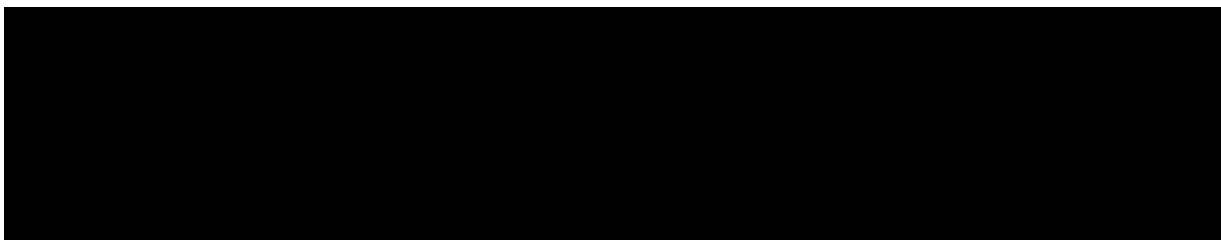
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From: [REDACTED]
Sent: Tuesday, May 07, 2019 12:42 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: RE: Updated 1572 OMB Expiration Date March 31, 2022

Hello,

Thank you for responding just to clarify I understand it should not be updated solely for the expiration date, but if the site has to update for another reason would it need to be on the new form. A site is stating they will not use it for updated form for ongoing studies.

Kind Regards,



From: OC GCP Questions <gcpquestions@fda.hhs.gov>

Sent: Tuesday, May 07, 2019 12:13 PM

To: [REDACTED]

Subject: Updated 1572 OMB Expiration Date March 31, 2022

Good afternoon –

You don't have to update the 1572 for the expiration date. However, the new form (expiration 2022) should be used for future new 1572 submissions.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA



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: Tuesday, May 07, 2019 11:42 AM

To: OC GCP Questions <gcpquestions@fda.hhs.gov>

Subject: Updated 1572 OMB Expiration Date March 31, 2022

Hello,

Are research sites required to utilize the updated FDA 1572, if there is a change to their 1572?

Kind Regards,

