

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: Question on the use of expired 1572
Date: Wednesday, April 24, 2019 11:56:12 AM
Attachments: [REDACTED]

Good morning again –

Sorry for the confusion. If the updated form is posted, that form should be used. However, it depends on when the 1572 form was completed and sent in to you. The updated form might not have been available. I would be ok at this point to accept the 1572 expired form information. But in the future, the updated form should be used.

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: Wednesday, April 24, 2019 11:51 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: RE: Question on the use of expired 1572

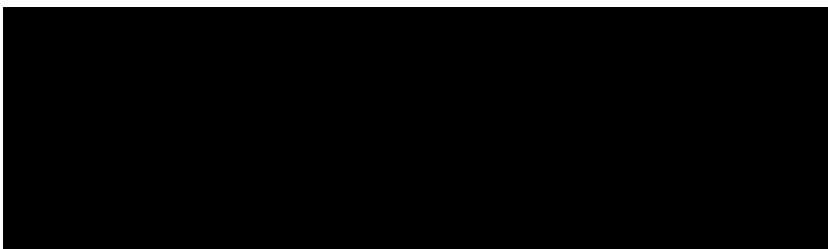
Hi,

So to confirm as long as the non-expired are posted and available on the fda.gov website we should not accept information provided on the expired 1572 forms?

Kind Regards,

[REDACTED]

[REDACTED]



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

Sent: Wednesday, April 24, 2019 10:41 AM

To: 

Subject: Question on the use of expired 1572


Good morning –

Please see the link below. The expired forms can still be used until the updated forms are posted.

<https://www.fda.gov/ForIndustry/FDABasicsforIndustry/ucm237984.htm>

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: 

Sent: Tuesday, April 23, 2019 1:22 PM

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

Subject: Question on the use of expired 1572

Hi,

We are having questions in our organization on if the expired 1572 (Expired 2/2019) can still be used for a certain period of time after the issue of the new Form 1572 (exp 3/31/2022)? Example: a clinical investigator submits a signed 1572 to the sponsor on 4/22/2019, but it is on the expired (2/2019) form 1572 template.

Kind Regards,

