

**From:** [OC GCP Questions](#)  
**To:** [REDACTED]  
**Subject:** RE: Form 1572 expiration date  
**Date:** Thursday, October 24, 2019 10:38:00 AM  
**Attachments:** [REDACTED]

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Dear [REDACTED] -

Thank you for your question. It is best to use the most current version of the FDA Form 1572 posted on the FDA web site at the time of initial signing, but there are times when the 1572 form has reached its expiration date and a new form has not been issued yet. During this lag in time, it is acceptable to use the expired form since a new version has not been posted yet and the expired form is the most current version available.

As you may know, FDA has guidance entitled, "Frequently Asked Questions – Statement of Investigator (Form FDA 1572)" (see <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/frequently-asked-questions-statement-investigator-form-fda-1572>). Question #s 7 and 16 may be of particular interest to you.

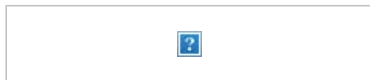
You may also want to discuss any questions you have about the 1572 form with the sponsor you are working with, since this form is one collected by the sponsor.

I hope this information is useful. If you need further information and/or have additional questions, please feel free to contact us at the official GCP mailbox, [gcp.questions@fda.hhs.gov](mailto:gcp.questions@fda.hhs.gov). You may also find it useful to access the set of redacted GCP e-mails found at <http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriesToFDAonGoodClinicalPractice/default.htm> since we find that many questions and concerns are repeated over time.

Best Regards,

Janet  
Janet Donnelly, RAC  
*Policy Analyst*

Office of the Commissioner  
Office of Good Clinical Practice  
U.S. Food and Drug Administration



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, October 22, 2019 4:02 PM  
**To:** OC GCP Questions <[gcpquestions@fda.hhs.gov](mailto:gcpquestions@fda.hhs.gov)>  
**Subject:** Form 1572 expiration date

Hello,

I have a question about Form 1572 OMB expiration date.  
Is the investigator required to sign the most current form?  
If an investigator signed a 1572 form after the OMB expiration date is the document is still count as effective?

I only know on the 1572 FDA guideline said the 1572 form do not need to sign a new 1572 when it reach the expiration date.  
Thank you!

