

**From:** [Brown, Sheila \(OGCP\)](#)  
**To:** [REDACTED]  
**Subject:** RE: 1572 form  
**Date:** Wednesday, September 14, 2016 8:43:00 AM

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Dear [REDACTED],

According to the current form 1572, issued February 2016, the previous edition of the form is obsolete. Therefore, IRBs and Sponsors should begin using the new 1572 form for **new** studies. The current form can be found on FDA's website at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM074728.pdf> .

You may also wish to review FDA's Information Sheet guidance, Frequently Asked Questions – Statement of Investigator (Form 1572), which can be found at <http://www.fda.gov/downloads/regulatoryinformation/guidances/ucm214282.pdf> . Q/A 16 addresses your question regarding ongoing studies. I have reproduced it here for your convenience:

**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.

For further questions about the form, please contact [DRUGINFO@fda.hhs.gov](mailto:DRUGINFO@fda.hhs.gov) .

I hope this information is helpful to you. If you need further assistance, please feel free to contact the GCP mailbox at [gcp.questions@fda.hhs.gov](mailto:gcp.questions@fda.hhs.gov) .

Best regards,

Sheila

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**From:** [REDACTED]  
**Sent:** Tuesday, September 13, 2016 8:28 AM  
**To:** OC GCP Questions; [gcp.questions@fda.gov](mailto:gcp.questions@fda.gov)  
**Subject:** 1572 form

What is the timeline for IRBs and Sponsors to request clinical research sites to use new amended 1572 form?