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

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According to the current form 1572, issued February 2016, the previous edition of the form is obsolete.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 .

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 .

Best regards,

Sheila

Sheila Brown, RN, MS
Policy Analyst, Office of Good Clinical Practice
Office of Special Medical Programs, Food and Drug Administration

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

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