From: OC GCP Questions
To: [redacted]
Subject: FW: Questions Regarding Form 1572
Date: Thursday, April 20, 2017 1:07:00 PM
Attachments: [redacted]

Dear [redacted] -

Thank you for your recent questions about the FDA Form 1572 which were forwarded to my office for a response. FDA has guidance titled, "*Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs, Frequently Asked Questions – Statement of Investigator (Form FDA 1572)*" that can be found at https://www.fda.gov/downloads/regulatoryinformation/guidances/ucm214282.pdf.

Question #7 addresses when a 1572 must be updated or a new 1572 completed and Question #16 specifically addresses your question about whether a new 1572 has to be signed when the OMB date on the form expires. I've copied both questions below for your reference:

> **7. When must a 1572 be updated or a new 1572 completed and signed by an investigator to reflect new or changed information?**
>
> 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.
>
> **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.

The most current version of the Form FDA 1572 that should be used is the one available at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM074728.pdf. The current 1572 form expires February 28, 2019. So if a sponsor was starting a study today, the sponsor would use the current 1572 found on FDA's web page. The expiration date merely reflects the U.S. government's Office of Management and Budget's (OMB's) clearance/reclearance of the form as an FDA form that meets the requirements of the Paperwork Reduction Act. FDA is required to submit a request for renewal of all forms no later than the expiration date on the most current form. However, the review and reapproval process, as well as issuance and posting of a new form, can often be delayed. I think that the previous version of the 1572 form had an expiration date of April 30, 2015 and was ok to use up until the most current version was posted back in April of 2016. In any case, there is no need to update the form after one with a new expiration date is issued.

Lastly, the FDA Form 1572 is a form the sponsor is responsible for obtaining (refer to 21 CFR 312.53(c)). Since the 1572 is a sponsor document, we recommend that you discuss your questions more thoroughly with them and suggest you have others from the site involved in the discussion since the investigator will be asked to sign the form and to comply with the investigational plan/protocol and pertinent regulations.

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. 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
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Policy Analyst

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