From: OC GCP Questions
To: [redacted]
Subject: RE: Updated 1572 required
Date: Wednesday, December 31, 2014 2:58:00 PM
Attachments: [redacted]

Dear [Redacted]-

Thanks for your follow up question. Doreen is out of the office this week so I will respond. Doreen previously shared with you that FDA has Information Sheet guidance for sponsors, clinical investigators, and IRBs titled, "*Frequently Asked Questions – Statement of Investigator (Form FDA 1572)*" that can be found at the following web location: http://www.fda.gov/downloads/regulatoryinformation/guidances/ucm214282.pdf. This guidance applies to clinical investigations conducted under 21 CFR Part 312 (Investigational New Drug Applications or IND regulations). It describes how to complete the Statement of Investigator form (Form FDA 1572).

Question #16 in section I of the guidance addresses your question about preparing and signing a new 1572 when the OMB expiration date on the form is reached (I copied the passage here for your reference):

> **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 Statement of Investigator, Form FDA 1572 (1572), is an agreement signed by the investigator to provide certain information to the sponsor and assure that he/she will comply with FDA regulations related to the conduct of a clinical investigation of an investigational drug or biologic. Since the 1572 is a sponsor form, I suggest you also consult any sponsor that you work with since different sponsors may have certain expectations for how and when their sites fill out and/or document changes in information to the 1572. However, as stated in the FDA guidance referenced above, there is no need to prepare and sign a new 1572 when the OMB expiration date has been reached. You may want to take a look at the referenced guidance as it may assist you with other questions that may come up.

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

Janet Donnelly, RAC, CIP
Policy Analyst, Office of Good Clinical Practice
Office of Special Medical Programs, Food and Drug Administration

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From: [Redacted]
Sent: Tuesday, December 30, 2014 2:35 PM
To: OC GCP Questions
Subject: RE: Updated 1572 required

Hello,

I had a follow up question to updating the 1572. If the current 1572 has expired, are sites required to submit one on the current 1572 that expires April 2015?

Thanks!

[Redacted]

From: OC GCP Questions [mailto:gcp.questions@fda.hhs.gov]
Sent: Thursday, November 20, 2014 11:59 AM
To: [Redacted]
Subject: Updated 1572 required

Good afternoon –

Based on the information in your email, it appears the 1572 does not need to be updated. The FDA 1572 guidance states- http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf

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.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [Redacted]
Sent: Wednesday, November 19, 2014 7:38 PM
To: OC GCP Questions
Subject: Updated 1572 required

Hello,

My company is asking sites who are participating in our clinical trial, to update the 1572 based on the new version that came out, that expires Apr 2015. We are asking the sites to update the 1572 to check section 8 for Phase 2 or 3. Our study is a phase 4. The sites have not previously checked that box because it is indicated in another section that the study is a phase 4. I am asking because we have sites refusing to update the 1572 as they state it is not required. If you could please let me know if this is a requirement of the FDA or seems to be just a requirement of the CRO, I would appreciate it so I know how to address the PIs/Sites that are refusing to update.

Thank you,

[Redacted]