From: OC GCP Questions
To: [redacted]
Subject: Question Regarding 1572 Versions
Date: Thursday, May 12, 2016 6:23:08 AM
Attachments: [redacted]

Good morning –

It is best to use the most current 1572 form. However according to the 1572 form guidance 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.

So there is no need to have the CI (PI) sign a new 1572 except for two scenarios mentioned above.

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

Kind regards,

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Office of Good Clinical Practice
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From: [redacted]
Sent: Wednesday, May 11, 2016 3:10 PM
To: OC GCP Questions
Subject: Question Regarding 1572 Versions

Hello,

I have a question regarding 1572s versions, and am hopeful you can shed some light. I understand

that GCP does not require a 1572 to be re-completed once the OMB expiration date has arrived. However, is a PI able to sign a 1572 form if it is not the most recent version on the FDAs webpage?

For example, a new FDA1572 form was recently made available on the FDA's webpage. The new 1572 has an expiration date of 28Feb2019. If a PI were to sign a new 1572 tomorrow, are they able to use the previous 1572 version which shows an expiration date of 30Apr2015? The only questions/answers I could find regarding this topic pertain to whether 1572 forms needed to be re-completed at the time of OMB expiration, which is different from what I would like to determine.

Any help you are able to send my way is greatly appreciated.

All the best,

[redacted]