From: OC GCP Questions
To: [redacted]
Subject: Question on submission of reportable changes to the FDA form 1572
Date: Friday, October 07, 2016 12:26:00 PM
[redacted]

Good afternoon –

Please see FDA's 1572 guidance.
http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf It states --

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.

You mention 312.30(e) which states at 30 day intervals when necessary…it also states "When several submissions of new protocols or protocol changes are anticipated during a short period, the sponsor is encouraged, to the extent feasible, to include these all in a single submission."

The sponsor should have an idea as to when new information should be submitted to the IND.

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

Kind regards,

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Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Friday, October 07, 2016 10:14 AM
To: OC GCP Questions
[redacted]

Subject: RE: Question on submission of reportable changes to the FDA form 1572

Good morning,
Can you please provide guidance on the submission of reportable changes (addition of new sub-investigator, IRB address change, addition of new clinical research lab) to the FDA form 1572.
Per guidance in 21CRF 312.30 (e) "..additional information may be grouped and submitted at 30 day intervals...".
Is there a specific time requirement from the receipt of this information by the sponsor to submission to FDA?

Thank you in advance for your input.

[redacted]

[redacted]