

From: OC GCP Questions
To: [REDACTED]
Subject: Form 1572 Question
Date: Wednesday, February 15, 2017 8:57:00 AM
Attachments: [REDACTED]

Good morning –

The 1572 form does not need to be updated. According to the 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.

Kind regards,

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This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: [REDACTED]
Sent: Monday, February 13, 2017 5:51 PM
To: OC GCP Questions
Subject: Form 1572 Question

Good Afternoon:

If we were to modify the title of a current protocol under an IND secondary to an amendment to the protocol but still leave the protocol number intact – on the form 1572 would that require active investigators to complete an updated form 1572 to incorporate the amended title to the protocol?

In reviewed the Information Guidance from May 2010, it appears it may not be necessary.

However, I'd be interested in your thoughts please.

Thank you

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]