From: OC GCP Questions
To: [redacted]
Subject: 1572 Question
Date: Friday, August 16, 2019 11:36:58 AM

Good morning –

We received many queries similar to yours. It can be frustrating on your part. The information in the FDA 1572 form guidance still applies. https://www.fda.gov/media/78830/download Specifically question # 7.

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,

Doreen M. Kezer, MSN

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Office of Good Clinical Practice

Office of the Commissioner, FDA

From: [redacted]
Sent: Friday, August 16, 2019 11:08 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Cc: CDER DRUG INFO <DRUGINFO@fda.hhs.gov>
Subject: 1572 Question

Good morning.

I would like to speak with someone regarding 1572 guidelines. In the *Information Sheet Guidance for Sponsors, Clinical Investigators, and IRB's: Frequently Asked Questions –*

Statement of Investigator (Form FDA 1572), there is guidance in Section I. General, Subsection 7 regarding "When must a 1572 be updated or a new 1572 completed and signed by an investigator to reflect new or changed information?" This guidance states that 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. Following this statement there are specific examples listed that *should not* lead to a new 1572 being produced, including an IRB address change, the addition of new subinvestigators, or the addition of a clinical research lab.

We are frequently asked by sponsors / CRO's to update our 1572 forms to reflect changes in our clinical research studies, including all of the examples listed by the FDA as reasons NOT to resubmit a new form. With all of the changes that occur during studies in the current research climate we may be asked to resubmit five or six new 1572's during a study. We respond to these requests with the FDA guidance on 1572's, and state that per that guidance we will document the changes in our clinical study records, with that documentation filed with the 1572 to be easily located by all parties. We argue that the 1572 is an agreement between the principal investigator and the FDA, and that an FDA document should be regulated by FDA guidelines alone. We have SOP's in place that state we will comply with FDA guidelines where they apply. Still, we receive a tremendous amount of pushback on this issue.

Please confirm that the information listed in the Statement of Investigator Information Sheet created on May 2010 still applies as outlined above. We would appreciate the confirmation as we strive to comply with FDA guidance.

Best regards,

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