From: OC GCP Questions
To: [redacted]
Subject: Investigator FDA 1572 Question
Date: Friday, July 19, 2019 2:16:50 PM

Good afternoon -

Please see FDA's guidance document for the 1572 form. https://www.fda.gov/media/78830/download . 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.

So, if you are adding a new subinvestigator a new 1572 form does not need to be completed. You can send the changes, including the 3455 form, to FDA in an information amendment or a protocol amendment. When you update the information, you should reference your IND number on the page.

Kind regards,

Doreen M. Kezer, MSN
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Office of Good Clinical Practice
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From: [redacted]
Sent: Thursday, July 18, 2019 5:45 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Investigator FDA 1572 Question

Good Evening,

I am writing to confirm the best way to send an FDA 1572 and 3455 for an investigator-initiated study. We have an additional sub investigator to add to our study and the removal of another. Should I send these forms directly to the FDA, because we do not have a study sponsor?

Thanks for the help.

Warmly,

[redacted]