From: OC GCP Questions
To: [redacted]
Subject: RE: FDA-1572
Date: Friday, September 27, 2019 9:08:00 AM
Attachments: [redacted]

Dear [redacted],
All of your questions have answers in FDA's information sheet guidance, *Frequently Asked Questions – Statement of Investigator (Form FDA 1572)*, which can be found at https://www.fda.gov/media/78830/download

I have listed the specific questions where you can find the answer below each of your questions (below).

I hope this information is helpful to you. If you need further assistance, please feel free to contact the GCP mailbox at gcp.questions@fda.hhs.gov .

Best regards,

Sheila

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From: [redacted]
Sent: Thursday, September 26, 2019 6:02 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: FDA-1572

Hello,

I'm seeking your help for the following questions in reference to Sponsor initiated clinical trials that are for Inestigational New Drug:

1) When sub-investigators are either added or removed from the study, we notify our IRB, but does a new 1572 need to be drafted to indicate the change in sub-investigators and re-signed/dated by the Investigator? See Q. 7 of the guidance cited above

2) Does the main Clinical Laboratory as listed in the CLIA certificate that represents the clinical facility hospital shown in Item #4 should be listed on the 1572? Example: Item#4 has [redacted] listed as the clinical hospital where the study will take place but [redacted] has a CLIA Certificate showing the main Laboratory address, therefore does both locations need to be listed? See Q 28 and 29 of the guidance cited above

3) Does the Pharmacy shipping address need to be listed on the 1572? This would be where the IP is received and prepared. See Q 33 of the guidance cited above

Thank you for your time.