From: OC GCP Questions
To: [redacted]
Subject: Initial Investigational Drug Shipment
Date: Tuesday, December 16, 2014 10:49:13 AM

Good morning --

FDA regulations under 312.30(c) states --

(c) New investigator . A sponsor shall submit a protocol amendment when a new investigator is added to carry out a previously submitted protocol, except that a protocol amendment is not required when a licensed practitioner is added in the case of a treatment protocol under 312.315 or 312.320. Once the investigator is added to the study, the investigational drug may be shipped to the investigator and the investigator may begin participating in the study. The sponsor shall notify FDA of the new investigator within 30 days of the investigator being added.

The sponsor should notifiy FDA by a protocol amendment. The amendment can be submitted to the FDA project manager that is overseeing the IND. The sponsor should have the name and address for this person in the IND documents.

Please also note, that if a new investigator is added to the IND, he/she must sign the 1572 form. Please see the 1572 guidance link below.

http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf

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

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.

-----Original Message-----
From: [redacted]
Sent: Monday, December 15, 2014 12:20 PM
To: OC GCP Questions
Subject: Initial Investigational Drug Shipment

I have a question regarding the requirement to notify FDA of a new investigator under 21 CFR 312.30(c). The regulations states that the sponsor should notify FDA “within 30 days of the investigator being added” to the study. How does the FDA define “being added”? I’m trying to understand the

trigger for this requirement.

Thank you very much for your help!