From: OC GCP Questions
To: [redacted]
Subject: FDA 1572 block 6
Date: Tuesday, September 15, 2015 1:16:21 PM

Good afternoon –

I can refer you to FDA's guidance on the 1572 form. (Link below)

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

33. Should pharmacists or research coordinators be listed in Section #6?

The decision about whether to list a pharmacist or research coordinator on the 1572 is a matter of judgment, dependent upon the contribution that the individual makes to the study. For example, a research pharmacist may prepare test articles and maintain drug accountability for many clinical studies that are ongoing concurrently at an institution. Because the pharmacist would not be making a direct and significant contribution to the data for a particular study, it would not be necessary to list the pharmacist as a subinvestigator in Section #6, but he/she should be listed in the investigator's study records.

Generally, a research coordinator has a greater role in performing critical study functions and making direct and significant contributions to the data. For example, a research coordinator often recruits subjects, collects and evaluates study data, and maintains study records. ***Therefore, the research coordinator should usually be listed in Section #6 of the 1572. [Emphasis added]***

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

Kind regards

Doreen M. Kezer, MSN
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Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Tuesday, September 15, 2015 10:41 AM
To: OC GCP Questions
Subject: FDA 1572 block 6
Importance: High

I'm trying to find out the FDA's requirement for adding coordinators to block 6 of the 1572 for clinical research. We have not added them and have not been asked by the sponsor to add them. The coordinators responsibilities include screening patients and informed consent. We prefer not to add them, but we want to adhere to FDA regulations concerning

this issue.
Thanks so much!
[redacted]