From: OC GCP Questions
To: [redacted]
Subject: 1572 question
Date: Wednesday, October 28, 2015 8:08:21 AM

Good morning –

The 1572 guidance (link below) states the following --

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

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.

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
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Tuesday, October 27, 2015 4:33 PM
To: OC GCP Questions
Subject: 1572 question

Hi,

We are wondering if study coordinators have to be on the 1572 if they are part of the consent process or can that be delegated by the PI on the delegation log.

Thank you for hopefully clarifying this issue.

[redacted]