From: OC GCP Questions
To: [redacted]
Subject: hello and request for clarification
Date: Wednesday, October 08, 2014 11:50:29 AM

Good morning [redacted] –

I discussed your email with my OGCP colleagues. We do not think that every study coordinator or research nurse should be listed on the 1572. It depends on their role in the study. As question 31 states in the guidance the decision to list an individual in Section #6 depends on his/her level of responsibility (i.e., whether he/she is performing significant clinical investigation-related duties). Since the 1572 form is a "sponsor" form the sponsor would also have a say as to who is listed on the form.

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: Monday, September 29, 2014 12:55 PM
To: [redacted]
Cc: [redacted]
Subject: hello and request for clarification

Dear Joanne,

Hope you are well and had a great summer (albeit too fast). And hopefully will see you at PRIMR in Baltimore?

I am writing for some help with a question that recently came up re: who should be listed on form FDA 1572, Section #6 Names of Sub-Investigators. During a recent FDA Inspection at BWH, the Inspector informed the site that the FDA wants not only licensed clinicians, but any study staff that handles and could manipulate study data to be listed on the 1572. We are particularly interested as to whether research coordinators should be listed on 1572.

We reviewed the May 2010 FDA guidance document Frequently Asked Questions – Statement of Investigator (Form FDA 1572) and noted the following two FAQs related to

Sub-Investigators:

31. Who should be listed as a subinvestigator in Section #6?

"The purpose of Section #6 is to capture information about individuals who, as part of an investigative team, will assist the investigator and make a direct and significant contribution to the data. The decision to list an individual in Section #6 depends on his/her level of responsibility (i.e., whether he/she is performing significant clinical investigation-related duties). In general, if an individual is directly involved in the performance of procedures required by the protocol, and the collection of data, that person should be listed on the 1572. For example, if the protocol notes that each subject needs to visit a specified internist who will perform a full physical to qualify subjects for the clinical investigation, that internist should be listed in Section #6."

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

"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."

Our interpretation of FAQ #31 is that the decision to list an individual in Section #6 depends on the individual's level of responsibilities (i.e., whether he/she is performing significant clinical investigation-related duties). Based on the qualifier "significant clinical investigation-related duties" we have not interpreted this to mean that a research coordinator should be listed as subinvestigator.
However, the answer to question #33 mentions research coordinators specifically and indicates that, in general, research coordinators (in contrast to pharmacists) should be listed as subinvestigators because they are often involved in recruitment of subjects, collection and evaluation of study data and maintenance of study records. These study-related activities are quite broad and, FAQ 33 unlike FAQ31, includes no qualifier or discussion of significant clinical investigation-related duties.

Additionally, we note that the Instructions for completion of the 1572 are along the lines of the first paragraph and do not mention research coordinators at all (http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM223432.pdf, field 6).

We would NOT typically advise our investigator that every study coordinator or research nurse be listed on 1572s. Doing so would be a major change, which is why we are writing

for clarification.

Thanks in advance and if it is easier to chat by phone, please just let me know.

Thank you.

[redacted]