From: OC GCP Questions
Sent: Wednesday, July 01, 2015 9:37 AM
To: [redacted]
Subject: RE: Research Pharmacists noted as Sub-Investigators

Dear [redacted],

I would refer you to the guidance document on Frequently Asked Questions – Statement of Investigator (Form FDA 1572) [http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf] for assistance. Subinvestigators would have a significant and direct impact on the data that is derived from the clinical investigation. See the following Q&A for further assistance with your question:

VII. SECTION #6: NAMES OF THE SUBINVESTIGATORS WHO WILL BE ASSISTING THE INVESTIGATOR IN THE CONDUCT OF THE INVESTIGATION(S)

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

FDA's regulation at 21 CFR 312.3(b) states: "In the event an investigation is conducted by a team of individuals, the investigator is the responsible leader of the team. 'Subinvestigator' includes any other individual member of that team." 21 CFR 312.53(c)(1)(viii) requires the investigator to provide "a list of the names of the subinvestigators (e.g., research fellows, residents) who will be assisting the investigator in the conduct of the investigation(s)."

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?

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.

I hope that this information is helpful. Please contact us at gcp.questions@fda.hhs.gov if you have further questions. Since many questions and concerns regarding good clinical practices have been addressed over time, some individuals may find it useful to access a set of redacted GCP inquiries found at the following web address: http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGoodClinicalPractice/default.htm .

Sincerely,

Bridget A. Foltz, MS, MT(ASCP)
Policy Analyst, Office of Good Clinical Practice
Office of the Commissioner, Food and Drug Administration

From: [redacted]
Sent: Monday, June 29, 2015 5:04 PM
To: OC GCP Questions
Subject: Research Pharmacists noted as Sub-Investigators

Hi

I have a question concerning who should be considered a sub-investigator on a clinical trial.

An auditor has suggested that research pharmacists who prepare infusion drugs for a clinical trial would meet the definition of a sub-investigator. The auditor acknowledges the current guidance document that notes pharmacists would not be making a direct and significant contribution to the study. However, the auditor notes that under the ICH/GCP definition of a subinvestigator includes trial-related procedures and notes that preparation of the IP is such a procedure. Also, the completion of drug dispensing and accountability forms are part of the pharmacists study tasks.

So based on the GCP definition and the CFR definition, the auditor is determining research pharmacists to be sub-investigators.

Would the FDA, based on both the CFR and GCP, want to see pharmacists who prepare infusions of IP and complete accountability and dispensing forms be treated as sub-Investigators?

Any input would be greatly appreciated.

Thanks,
[redacted]