From: OC GCP Questions
Sent: Thursday, March 06, 2014 9:26 AM
To: [redacted]
Subject: RE: FDA 1572- home visits

Dear [Redacted],

To respond to your question, I looked at questions 32 and 33 in FDA's "Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs: Frequently Asked Questions – Statement of Investigator (Form FDA 1572)" (http://www.fda.gov/downloads/regulatoryinformation/guidances/ucm214282.pdf). Those questions and answers are restated below:

> **32. Should research nurses, other nurses, residents, fellows, office staff, or other hospital staff be listed in Section #6?**
>
> Hospital staff, including nurses, residents, or fellows and office staff who provide ancillary or intermittent care but who do not make a direct and significant contribution to the clinical data, do not need to be listed individually. It is not necessary to include in this section a person with only an occasional role in the conduct of the research, e.g., an on-call physician who temporarily dealt with a possible adverse effect or a temporary substitute for any research staff (see ICH E3, Section 6) (http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073113.pdf).
>
> Concerning staff residents on rotation, it may be difficult to prospectively identify those individuals who might perform specified protocol procedures or collect clinical data. Specific names of the rotational staff do not have to be listed in Section #6. Instead, to successfully address this scenario, the names of rotational individuals and the procedures they are expected to perform should be included in the clinical study records. This information should also be sent to the sponsor for submission to FDA in, for example, an information amendment.
>
> **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.

You state that the qualified home health nurse performs protocol required procedures. As stated in the answer to question 33 above, whether to include on the 1572 the nurse and the agency is a matter of

judgment depending upon the contribution that the individual makes to the study. From the information given, it appears that the nurse is making a direct and significant contribution to the data for the particular clinical trial. Therefore, the information about the nurse should be included in Section #6 of the 1572.

I hope this information is helpful to you. If further assistance is needed, please feel free to contact us once again at the official GCP mailbox, gcp.questions@fda.hhs.gov.

Best regards,
Kathleen Pfaender, RN, JD
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of Medical Products and Tobacco
Federal Food and Drug Administration
WO32/5129
301-796-8346

From: [Redacted]
Sent: Wednesday, March 05, 2014 3:29 PM
To: OC GCP Questions
Subject: FDA 1572- home visits

Hello,
Some protocol required procedures for a particular clinical trial can be done in a patient's home by a qualified home health nurse. The nurse is delegated the tasks by the PI as documented on the site specific delegation of responsibilities log. Does the agency from where the nurse comes from need to be on the 1572? If yes, which box?
Thank you!

[Redacted]