From: OC GCP Questions
To: [redacted]
Subject: RE: Who goes on the FDA Form 1572
Date: Monday, January 28, 2019 3:54:19 PM
Attachments: [redacted]

Good afternoon,

If you read earlier in the section of the 1572 Guidance you have posted below, it states that "*The purpose of Field 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).

If there is a continued question in regards to whether or not an individual should be listed under Section #6, I would recommend that you discuss your concerns directly with the sponsor of the study as the 1572 is an agreement between the sponsor and clinical investigator responsible for the form.

Sincerely,
Bridget

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From: [redacted]
Sent: Wednesday, January 02, 2019 7:56 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Who goes on the FDA Form 1572

Hello again.

I have a quick question regarding **who goes on the 157**2. Per the FDA guidance:

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 Field 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 Field 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 Form FDA 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 Field 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.

When you say "and collection of the data" are you saying we need to put the data entry staff onto the 1572? They are simply transcribing what is in the source documents into the database. They are not making any clinical decisions nor are they involved in performance of protocol required procedures. To me it doesn't seem to warrant adding them in but I would like your opinion.

Thanks again,