From: OC GCP Questions
To: [redacted]
Subject: Question Regarding Investigator 1572 Requirements
Date: Friday, February 20, 2015 11:48:28 AM

Good morning –

The "Principal Investigator" (Clinical Investigator) signs the form and the investigators are listed as sub-investigators on the form. Please see FDA's 1572 guidance guidance document below for reference.

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

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.

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: Friday, February 20, 2015 8:42 AM
To: OC GCP Questions
Subject: Question Regarding Investigator 1572 Requirements

There seem to be different interpretations within the clinical trial community regarding the FDA's guidance on 1572s and whether or not each investigator at a study site should be completing their own 1572.

We are requesting specific guidance on the following question- For a multi-center clinical trial in

which there may be several investigators at a particular site who conduct study visits and independently administer study treatments and consent participants, should each investigator at a site complete their own 1572? Each site does have a designated "principal investigator", as listed for the IRB, who is ultimately responsible for the conduct of the trial at their site, so alternatively, is it sufficient to only have the principal investigator sign a 1572 with the other investigators listed as "sub-investigators"?

Furthermore, if each investigator does sign their own 1572, do investigators at the same site need to be listed on each other's 1572s as sub-investigators?

[redacted]

[redacted]