From: OC GCP Questions
To: [redacted]
Subject: 1572 Question in relation to Sub-Is
Date: Friday, September 13, 2019 12:41:57 PM
Attachments: [redacted]

Good afternoon –

Please see FDA's 1572 Form guidance. https://www.fda.gov/media/78830/download 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.

It appears based on the limited information in your email, that the specialist should be listed on the 1572 form as the subjects are required to see this person before and at the end of the trial.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Friday, September 13, 2019 10:01 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: 1572 Question in relation to Sub-Is

Hello,

If our research protocol require a subject see a specialist, at another location, for an exam in the

beginning and at the end of the trial, does this specialist need to be listed as a Sub-I on the 1572?

[redacted] / Best Regards,

[redacted]