From: OC GCP Questions
Sent: Wednesday, January 07, 2015 10:55 AM
To: [redacted]
Subject: 1572 Section 6

Good morning –

Please see the FDA guidance for the 1572 form. http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf
Section #6 issues start on page 13 of the guidance. It states --

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.

You will have to determine the level of responsibility of the individuals based on the procedures required by the protocol.

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: Tuesday, January 06, 2015 12:09 PM
To: OC GCP Questions
Subject: 1572 Section 6

To Whom it May Concern:

I have read previous emails inquiring about section 6 of the 1572 including the responses that are located on the website. Could you
please confirm that anyone that is directly involved with a subject (i.e.Completing scales, taking vitals, performing ECGs, taking blood samples,etc) should and/or must be listed in section 6, even though they are not a direct substitute for the Principal Investigator? It is my understanding that anyone involved in the study, with the exception of someone limited to entering data (no direct involvement with the subject) to the CRF/eCRF must be listed.

Thank you.