From: OC GCP Questions
To: [redacted]
Subject: DOR 1572
Date: Friday, September 13, 2019 12:46:58 PM
Attachments: [redacted]

Good afternoon –

Please see FDA's 1572 form guidance document https://www.fda.gov/media/78830/download Please see question 31 and 32.

In question 31 it states –
…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…

It might be helpful for you to review the entire guidance. If you are not the sponsor of the study, the 1572 form is a sponsor form. You can always consult the sponsor.

Kind regards,

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FDA U.S. FOOD & DRUG ADMINISTRATION

From: [redacted]
Sent: Friday, September 13, 2019 11:04 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: DOR 1572

Is there a way to tell (based on the DOR duties) which people on a DOR should also be listed on the 1572?
Would it only be those who are A (obtain consent) and D (prescribe study drug)? Would any other duty be mandatory?

[redacted]