

From: OC GCP Questions
To: [REDACTED]
Subject: section 6 1572
Date: Thursday, January 12, 2017 9:04:00 AM
Attachments: [REDACTED]

Good morning –

Who should be listed in Section 6 depends on his/her level of responsibility for study related procedures. The sponsor should decide who should be listed as the 1572 form is a sponsor form.

Please see the guidance document below -- specifically starting on page 13 that discusses Section 6.
<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf>

I hope this information is helpful.

Kind regards,

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From: [REDACTED]
Sent: Tuesday, January 10, 2017 1:31 PM
To: OC GCP Questions
Subject: section 6 1572

Hi,

I had a question regarding section 6 of the 1572. I am having trouble with a dispute on who should be listed. I understand that the FDA asks for anyone that contributes data to be listed. However, as someone who works at a CRO is not, ultimately, a site/ principal investigator judgement call on who should be listed in section 6?

Thanks,

[REDACTED]