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

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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,

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




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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]