

From: OC GCP Questions
To: [REDACTED]
Subject: Sub-I's listed on 1572
Date: Friday, September 23, 2016 12:20:00 PM

Good afternoon –

It would be helpful for you to review FDA's 1572 guidance.
<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf> Please see section #6 starting on page 13. The guidance gives you regulatory citations.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

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From: [REDACTED]
Sent: Friday, September 23, 2016 10:32 AM
To: OC GCP Questions
Subject: Sub-I's listed on 1572

Greetings-

Is there some place in the regs that states that by virtue of being listed in Box #6 on the 1572 all sub-Is are affiliated with the PI who's address is listed in Box #1 of the 1572?

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]