

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: Guidance on FDA Form 1572 Question
Date: Monday, October 05, 2015 6:44:14 AM

Good morning –

There is no requirement on the 1572 form to list affiliations of study staff with the research facility(ies). However the sponsor may choose to do so if they want. Please see the guidance document on the 1572 form. (Link below)

<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf>

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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Office of Good Clinical Practice
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This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: [REDACTED]
Sent: Friday, October 02, 2015 2:04 PM
To: OC GCP Questions
Cc: [REDACTED]
Subject: Guidance on FDA Form 1572 Question

Good Afternoon,

I hope all is well with you!

I am also hoping that you will be able to aid me by providing a response to the question below.

We at [redacted] have a guidance in which we ask a research site listed in box 3 of the 1572 have an affiliated PI and/or Sub-I listed on the form (either in Box 1 or 6).

However, we have a site that has listed a research site in box 3, but none of the investigators (PI or Sub-Is) have a direct affiliation with the site location.

Can you please advise if this violates any FDA or GCP regulation?

[REDACTED]