

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: 1572 Question
Date: Tuesday, July 29, 2014 10:51:09 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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Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

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: ØYXUMXQ
Sent: Monday, July 28, 2014 6:33 PM
To: OC GCP Questions
Subject: 1572 Question

Hello,

Do all persons in Box 6 of the 1572 need to be affiliated with all facilities in Box 3?

The sponsor is asking for a memo of affiliation for all study staff listed on the 1572.

Thank you.

Best regards,

ØYXUMXQ