

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: 1572/Home Health Question
Date: Monday, December 07, 2015 6:09:00 AM

Good morning –

Based on the information in your email it is appropriate to list the home health company in box 4 on the 1572 form.

Kind regards,

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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: [REDACTED]
Sent: Thursday, December 03, 2015 11:46 AM
To: OC GCP Questions
Subject: 1572/Home Health Question

I am working on a study where a home health nurse will be visiting the patient's home for periodic pk draws. These nurses will only be drawing and shipping the pk samples; no analysis of the samples will be conducted by them. We have listed the main address of the home health company in box 4 of the 1572. Is this what you would recommend or would you recommend that the home health company be listed in box 3 (even though no study-related activities are taking place there and the PI cannot show oversight at that location)?

Thank you,

[REDACTED]