

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: Home health care provider and 1572
Date: Wednesday, October 22, 2014 2:14:18 PM

Good afternoon --

Generally the home health agency is not required to be listed on the 1572 form. Additionally the subject's home address does not need to be listed on the 1572.

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

Kind regards,

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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: ~~OFYXUMWXQ~~
Sent: Tuesday, October 21, 2014 3:13 PM
To: OC GCP Questions
Subject: Home health care provider and 1572

Dear FDA GCP Hotline,

We utilize a home health care provider to offer an optional service to take some blood draws at patient homes. The CRO we have hired to manage the study commented that the provider should be listed in section 3 on the Form FDA 1572. However the home health care provider is not evaluating patients or analyzing data thus we do not feel it is appropriate to list them as a facility where the clinical investigation is being conducted. The use of home health services is offered as optional for patients to ease the burden of having to travel to our clinical sites.

The home health care provider has been listed on the Delegation of Authority log at the sites using the service. Do we also need to include them in section 3 on the Form FDA 1572?

Thank you and best regards,