

From: OC GCP Questions
To: [REDACTED]
Subject: FDA 1572 completion - section # 6
Date: Tuesday, October 11, 2016 1:18:00 PM
Attachments: [REDACTED]

Good afternoon –

Please see FDA's guidance on the 1572 form.

<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf> Specifically question 33.

Kind regards,

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From: [REDACTED]
Sent: Monday, October 10, 2016 6:08 AM
To: OC GCP Questions
Subject: FDA 1572 completion - section # 6

Dear Sir and Madam

Would you please direct me who as an individual should be listed in the section # 6 of the FDA 1572 form, especially for the pharmacist.

In a clinical trial, when the pharmacist is responsible for drug reconstitution (e.g.: dilution with saline solution to prepare the required dose to be administered according to the subjects weight as per the study protocol) and maintaining the drug accountability records, should the pharmacist in this case be listed in the section # 6?

Thank you kindly,

[REDACTED]

[REDACTED]