

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: 1572 Question
Date: Tuesday, December 09, 2014 11:48:04 AM

Good morning --

To respond to your question, I reviewed the regulations in Title 21 Code of Federal Regulations (CFR) §§ 312.53(c)(2) and 812.43(c)(1). Those regulations do not include a requirement for updating an investigator's curriculum vitae.

For helpful information, please see the "Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs – Frequently Asked Questions – Statement of Investigator (Form FDA 1572)", May 2010, at <http://www.fda.gov/downloads/regulatoryinformation/guidances/ucm214282.pdf>. In particular, see question # 23 and the answer on page 11, which is restated below:

*23. Does the CV or other statement of qualifications need to be updated during a clinical study?
No. FDA regulations do not require a CV or other statement of qualifications to be updated during a clinical study.*

You also may be interested in the response to question # 24 in this guidance document, as follows:

*24. Are CVs required to be signed and dated?
No. FDA regulations do not require a CV to be signed and dated. The investigator's dated signature on the [Form FDA] 1572 is sufficient to attest to the accuracy of the CV or other statement of qualifications submitted with the 1572.*

I hope this information is helpful to you. If further assistance is needed, please feel free to contact us once again at the official GCP mailbox, gcp.questions@fda.hhs.gov.

Best 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: [redacted]
Sent: Friday, December 05, 2014 7:03 PM
To: OC GCP Questions
Subject: 1572 Question

When a study has 2 or more updated FDA Form 1572, should there be CVs for each 1572 or the most current?