

From: OC GCP Questions
To: [REDACTED]
Subject: Updated CV Question
Date: Monday, October 16, 2017 8:23:21 AM
Attachments: [REDACTED]

Good morning –

Please see FDA guidance document on the 1572 form.
<https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf> It states --

22. What is the purpose of Section #2?

Section #2 requires the investigator to attach a curriculum vitae (CV) or other statement of qualifications, showing the education, training and experience that qualifies the investigator as an expert in the clinical investigation of the drug/biologic for the use under investigation. Information identified in this section and attached to the 1572 enables the sponsor to assess an investigator's qualifications.

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.

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 1572 is sufficient to attest to the accuracy of the CV or other statement of qualifications submitted with the 1572.

There is no FDA requirement to update the CVs every two years.

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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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: Sunday, October 15, 2017 8:41 PM
To: OC GCP Questions
Subject: Updated CV Question

Good day. Is it a requirement that sites update their study staff member CV's every two years from the date noted on their CV?

Is it required that all study staff members participating on the clinical trial (who are not noted as sub-I's on

the FDA Form 1572) have a CV on file?

Thanks,

[REDACTED]