

**From:** [OC GCP Questions](#)  
**To:** [REDACTED]  
**Subject:** Recommendations for CV question  
**Date:** Thursday, November 09, 2017 8:28:00 AM  
**Attachments:** [REDACTED]

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Good morning –

FDA does not have a recommendation. FDA's 1572 guidance states the following.

<https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf>

**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.

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.

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**From:** [REDACTED]  
**Sent:** Thursday, November 09, 2017 7:17 AM  
**To:** OC GCP Questions <gcp.questions@fda.hhs.gov>  
**Subject:** Recommendations for CV question

Good morning,

I was wondering what the guidance or recommendation is regarding the length of time studies should remain on a CV? I know the purpose of the CV is to show the training and experience in conducting research studies and experience with an indication, but is it acceptable to the FDA, upon auditing, for the CV to include only the last 10-15 years of study history or should it maintain all study histories even dating back to the 70s?

I appreciate your assistance in this matter.

[REDACTED]