

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: CVs of the trial site staff members listed on the Delegation Log
Date: Friday, July 10, 2015 1:56:17 PM

Good afternoon –

Per FDA regulations just the investigators and sub-investigators, however sponsors often times collect CVs for other staff members as well.

The sponsor is required to obtain information from the investigator, including "A curriculum vitae or other statement of qualifications of the investigator showing the education, training, and experience that qualifies the investigator as an expert in the clinical investigation of the drug for the use under investigation." (See 21 CFR 312.53(c)(2).) While the regulations do not indicate that the statement of qualifications (or CV) needs to be signed, they do require that the investigator sign the statement of investigator (Form FDA 1572). (See 21 CFR 312.53(c)(1).)

The regulations do not include a requirement to update the statement of qualifications (or CV). However, FDA does expect an investigator to be in compliance with any state or local laws or requirements as part of being qualified. Therefore, an investigator (or a member of the investigator's staff) would need to maintain a medical license or other certification that is necessary to perform the study (for example, to diagnose or treat a patient). If the license is subject to renewal, then a current license would be needed in order to be in compliance with the local requirements. So, although not specified in FDA's regulations, in order to be qualified, an investigator or subinvestigator would need to maintain any required state or local licenses or certifications needed to perform the clinical tasks necessary to conduct the study.

FDA also has various guidance documents that mention the investigator's qualifications and curriculum vitae. I listed a few of them below for your reference (NOTE: this is not meant to be an all-inclusive list):

- ICH GCP E6 Good Clinical Practice: Consolidated Guidance, (which is recognized as official FDA guidance) – see sections 3.1.2, 3.1.3, 4.1.1, 8.2.10, and 8.3.5. You can access this guidance at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073122.pdf>
- Guidance for IRBs, Clinical Investigators, and Sponsors – IRB Responsibilities for Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the Determination of Whether an IND/IDE is Needed. You can access this guidance at <http://www.fda.gov/downloads/regulatoryinformation/guidances/ucm328855.pdf>.
- Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs – Frequently Asked Questions – Statement of Investigator (Form FDA 1572). You can access this guidance at <http://www.fda.gov/downloads/regulatoryinformation/guidances/ucm214282.pdf>

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

Kind regards,

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Office of Good Clinical Practice
Office of the Commissioner, FDA

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, July 10, 2015 12:30 PM
To: OYXUM/XQ
Cc: OC GCP Questions
Subject: CVs of the trial site staff members listed on the Delegation Log

Hello,

I emailed gcp.questions@fda.hhs.gov and got response that email can't be deliver (please see below). Whoever will receive the below question please forward to the proper FDA person! In advance thank you for help.

I have a question regarding a Curriculum vitae?

We are conducting a trial where Curriculum vitae were collected only for the Principal Investigator and Sub-investigators and were not collected CVs of the other trial staff listed on the site Delegation Log.

What would you recommend, to collect CVs of all trial staff members listed on the site Delegation Log? or to collect CVs of the Principal Investigator and Sub-investigators only ?

Kind regards,

[REDACTED]