From: OC GCP Questions
To: [redacted]
Subject: Current CVs
Date: Tuesday, June 24, 2014 12:05:02 PM

Good morning--
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.

The inclusion of specific information (e.g., clear affiliation with one of the study sites stated by name and address) in the curriculum vitae for the clinical investigator, subinvestigator, and associated study staff is usually a requirement of the sponsor, CRO, and/or the IRB.

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

Kind regards,

Doreen M. Kezer, MSN
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Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [Redacted]
Sent: Tuesday, June 24, 2014 10:57 AM
To: OC GCP Questions
Subject: Current CVs

Hi,

I was wondering if the FDA has a position on what constitutes a "current" CV.

The ICH E6 guidance doesn't specify what would be current and what would not be current.

I've frequently heard people ask for the CVs to be current within 2 years of when an investigator comes onto a clinical study but haven't seen it in any of the guidances on the subject.

Thanks for your input,
[redacted]