From: OC GCP Questions
To: [redacted]
Subject: RE: CV question
Date: Thursday, October 05, 2017 11:52:08 AM
Attachments: [redacted]

Dear [redacted] -

Thank you for your question. While the FDA regulations and various guidance documents mention the curriculum vitae of the clinical investigator, they are not so detailed as to address the specific content to be included in the curriculum vitae.

The FDA regulations for drugs, including biologics [see 21 CFR 312.53(a)], as well as the regulations for devices [see 21 CFR 812.43(a)], require that sponsors select investigators qualified by training and experience as appropriate experts to investigate the drug/biologic/device. The drug regulations at 21 CFR 312.53(c)(2) also require that the sponsor obtain the investigator's 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. The device regulations at 21 CFR 812.43(c)(1) and (2) require the sponsor to obtain a signed agreement that includes the investigator's curriculum vitae and, where applicable, a statement of the investigator's relevant experience, including the dates, location, extent, and type of experience. If you would like to access the noted regulations electronically, see https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=312 for drugs/biologics and https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=812%20for%20devices for devices.

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 https://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 https://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 https://www.fda.gov/downloads/regulatoryinformation/guidances/ucm214282.pdf.

The inclusion of specific information in the curriculum vitae for the clinical investigator (e.g., listing the name and address to show clear affiliation with the study site(s)) is usually a requirement of the sponsor, CRO, and/or the IRB. You should consult your sponsor/CRO and IRB with your question to determine what information they may require.

I hope this information is useful. If you need further information and/or have additional questions, please feel free to contact us at the official GCP mailbox, gcp.questions@fda.hhs.gov. You may also find it useful to access the set of redacted GCP e-mails found at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGoodClinicalPractice/default.htm since we find that many questions and concerns are repeated over time.

Best Regards,

Janet
Janet Donnelly, RAC
Policy Analyst

Office of the Commissioner
Office of Good Clinical Practice
U.S. Food and Drug Administration

[redacted]

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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: Wednesday, October 04, 2017 2:25 PM
To: OC GCP Questions
Subject: CV question
Importance: High

Good morning,

We are a research department that does research out of 2 different locations. If a study is only at one site, do addresses of both locations need to be on the CV of the investigator?

Thanks,

[redacted]