From: OC GCP Questions
To: [redacted]
Subject: Delegation of Authority Log Question
Date: Monday, March 27, 2017 10:08:00 AM

Good morning -

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

FDA regulations provide for some flexibility in how a clinical investigator's qualifications are documented. The pertinent regulations for drug studies are found at 312.23(6)(iii)(b) which requires the sponsor to include the following information in the protocol:

(b) The name and address and a statement of the qualifications (curriculum vitae or other statement of qualifications) of each investigator, and the name of each sub-investigator (e.g., research fellow, resident) working under the supervision of the investigator; the name and address of the research facilities to be used; and the name and address of each reviewing Institutional Review Board.

Sponsors are also required under 312.53(c)(2)to obtain the following information from the investigator:

(2) Curriculum vitae. 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.

The purpose of these requirements is to demonstrate that only investigators qualified by training and experience as appropriate experts to investigate the drug are selected. As you can see both regulations permit the use of a CV or other statement of qualifications for this purpose.

There is no specific requirement to sign and date a CV itself, however, I would point out that sponsors must obtain a signed and dated statement of investigator (FDA FORM 1572) which does include, as an attachment under block #2, a CV or statement of qualifications. In this sense, this information would be submitted under the investigator's dated signature.

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

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

-----Original Message-----
From: [redacted]
Sent: Thursday, March 23, 2017 5:50 PM
To: OC GCP Questions
Subject: Delegation of Authority Log Question

Good day. Is it a requirement to have on file a CV for each study staff member that signs/date the delegation of authority log that performs a study related procedure for any clinical trial?

[redacted]