From: OC GCP Questions
To: [redacted]
Subject: 1572 ITEM 4 Clinical Laboratory Facility - Clinical Research
Date: Tuesday, December 03, 2019 1:02:44 PM

Good afternoon –

Thank you for your email. Per FDA regulations just the investigators and sub-investigators need to have CVs on file, 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).)

Please see FDA's 1572 guidance. https://www.fda.gov/media/78830/download It states -

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.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
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From: [redacted]
Sent: Tuesday, December 03, 2019 10:25 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: 1572 ITEM 4 Clinical Laboratory Facility - Clinical Research

Good Morning:

Per protocol, the site sends study subjects to a local Imaging facility to have their MRI and/or PET scans performed at that facility. Per Sponsor, the site adds the facility to Item 4. Other vendors were already on the 1572 provided by the Sponsor.

My question is: **Does the site have to collect CV's, Licenses, etc. from the local Imaging Facility for the Investigator Site File since they are considered a vendor?**

Many Thanks,

[redacted]