From: OC GCP Questions
To: [redacted]
Subject: CVs and Financial Disclosures
Date: Wednesday, September 26, 2018 1:14:00 PM

Good afternoon -

I conferred with an OGCP colleague. If the SubCIs did not participate is the study, you are not required to retain their CVs or FD documents. Please see the additional information below.

Sponsors are not required to collect CVs for subinvestigators. You are correct about confirming the investigators are qualified by training and experience. FDA's regulations do not specifically address either CV's or medical licenses but do require that investigators be qualified by training and experience as appropriate experts to investigate the drug (21 CFR 312.53(a)). The sponsor includes in the IND submission to FDA, "The name and address and a statement of qualifications (curriculum vitae or other statement of qualifications) of each investigator, and the name of each subinvestigator (e.g., research fellow, resident) working under the supervision of the investigator..." (see 21 CFR 312.23(b)). Note that the regulations do not require the submission of the qualifications of subinvestigators.

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 guidance on Financial disclosure

https://www.fda.gov/downloads/regulatoryinformation/guidances/ucm341008.pdf It states –

FDA generally expects that applicants will be able to provide this information. Under 21 CFR §§ 312.53(c), 812.20(b)(5) and 812.43(c), a sponsor is required to obtain clinical investigator financial information before allowing the clinical investigator to participate in a covered clinical study.

B.8 Q: Is clinical investigator financial disclosure information required in IND or IDE applications?

A: No, IND/IDE sponsors are not required to submit information regarding clinical investigator financial interests or arrangements in IND or IDE applications. They are, however, required to collect this information before a clinical investigator **participates** [emphasis added] in a clinical study (see 21 CFR §§ 312.53(c)(4), 812.20(b)(5), and 812.43(c)(5)), and clinical investigators are required to disclose financial information to sponsors (see 21 CFR §§ 312.64(d) and 812.110(d)). The information need not be submitted to FDA until a marketing application is submitted containing the results of the covered clinical study (21 CFR § 54.4).

Study sponsors are encouraged to consult with FDA prior to and during clinical studies about the management of specific situations involving potential bias on the part of a clinical investigator. During these consultations, FDA staff should focus on the protection of research subjects and the minimization of bias from all potential sources.

If the site is not going to keep specific trials documents, the site should get approval from the sponsor.

Additionally, the relevant US FDA regulations on record retention for clinical trials documents are as follows:

For drug and biologic studies, 21 CFR 312.62(c) states: "Record retention. An investigator shall retain

records required to be maintained under this part for a period of 2 years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified."

As you will note, the retention period is dependent on whether the data will be used to support a marketing application with FDA. The sponsor is usually the only party totally knowledgeable about the status of its investigational product (e.g., whether it has been approved for marketing, whether the sponsor no longer intends to seek marketing approval, etc.). Therefore, it is best to check with the study sponsor regarding the status of the investigational product and the need to retain the study records. You should check with each of the study sponsors before discarding any study files. FDA regulations do not specifically address what documents need to be maintained at time of destruction.

I hope this information is helpful.

Kind regards,

Doreen M. Kezer, MSN

Senior Health Policy Analyst

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.

-----Original Message-----

From: [redacted]

Sent: Monday, September 24, 2018 9:15 PM

To: OC GCP Questions <gcpquestions@fda.hhs.gov>

Subject: CVs and Financial Disclosures

Dear FDA Representative,

Can you please confirm that there is no regulatory obligation for a Principal Investigator/clinical research site to maintain records of qualifications (i.e., CVs) and financial disclosure forms for individuals listed in the Form FDA 1572 box 6 (subinvestigators) if those individuals did NOT participate in the study? Is it not true that they only need to provide evidence that individuals who participated were trained and qualified prior to performing their delegated tasks if they participate in the study and to complete financial disclosure in accordance with regulatory requirements if they participate? Would there be any rationale for keeping anything pertaining to individuals who did not participate (other than the PIs original signed 1572, which may include names of people who later do not participate)? I cannot think of any reason, and it clutters the sites files with many unnecessary records. The site has clearly documented that the individuals did not participate.

Thank you,

[redacted]