From: OC GCP Questions
To: [redacted]
Subject: Medical Licenses in Clinical Trials
Date: Tuesday, April 25, 2017 1:14:00 PM
Attachments: [redacted]

Good morning –

This is what we have said in the past regarding medical licenses.

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).)

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.

The qualifications of study staff are not specifically addressed in the regulations. The regulations, however, require the investigator to commit to personally conduct or supervise the investigation (21 CFR 312.53(c)(1)(vi)(c)). When an investigator delegates study-related tasks, the investigator is responsible for providing adequate supervision of those to whom tasks are delegated. One of the areas that FDA looks at in assessing the adequacy of supervision by an investigator is whether individuals who were delegated tasks were qualified to perform such tasks. The investigator should ensure that any individuals to whom a task is delegated are qualified by education, training and experience to perform the delegated task, including state licensure where relevant. Therefore, although the regulations do not specifically require information on the qualification of study staff, maintaining records that indicate that study staff are qualified to perform the study tasks delegated to them is one thing an investigator can do in demonstrating proper supervision. [You may want to view FDA's guidance document titled, "Investigator Responsibilities - Protecting the Rights, Safety, and Welfare of Study Subjects," available at www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf, for more information on appropriate supervision.]

Although FDA's regulations do not specifically address maintaining CV's and medical/professional licenses in regulatory files, the FDA recognized guidance, ICH E6, "Good Clinical Practice: Consolidated Guidance" (available at www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf)

does recommend, in section 8.2.10, that the investigator and sponsor maintain "curriculum vitae and/or other relevant documents evidencing qualifications of investigator(s) and subinvestigators" to "document qualifications and eligibility to conduct trial and/or provide medical supervision of subjects."

Regarding your final question, whether or not research coordinators should be added to the Form FDA 1572 depends on the study related tasks that they perform. The FDA guidance document titled, "Frequently Asked Questions - Statement of Investigator (Form FDA 1572)," which is available at www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf, provides guidance on who should be listed as a subinvestigator. Please note that the guidance provided is based more on the nature of an individual's duties in the clinical trial rather than on a particular title. See particularly the response to question 33, which discusses research coordinators and identifies the functions that would cause a research coordinator to be considered a subinvestigator and necessitate his or her being listed on the Form FDA 1572. Additionally, the responses to questions 31 and 32 may be helpful.

Please note that guidance represents the agency's current thinking on a topic and does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Kind regards,

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From: [redacted]
Sent: Monday, April 24, 2017 1:30 PM
To: OC GCP Questions
Subject: Medical Licenses in Clinical Trials

Hello,

I am from [redacted] looking for FDA guidance regarding acceptable proof of active medical licenses for physician investigator in FDA regulated clinical trials. The college of physicians and surgeons o[redacted] has stopped issuing hard copies of medical licenses to physicians but they publish the active registrants on their website without indicating the start and expiry date.

In order to adequately document a record of the medical license in the Trial Master File, what is FDA's requirement for acceptable proof of active medical license, in consideration of the above change?

Regards,
[redacted]