From: OC GCP Questions
To: [redacted]
Cc: CDER DRUG INFO
Subject: Question on submission of investigator information to FDA for IND protocol investigators, domestic and foreign
Date: Tuesday, September 30, 2014 10:32:42 AM

Good morning –

The regulations do not specifically include what should be included in the statement of qualifications. 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.

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

The inclusion of specific information (e.g., clear affiliation with one of the study sites stated by name and address) in the curriculum vitae for the clinical investigator, subinvestigator, and associated study staff is usually a requirement of the sponsor, CRO, and/or the IRB.

For specific questions related to your IND (amendments, simplifying submissions) it is best for you to contact the assigned FDA Project Manager for that IND to get answers to your specific questions as they will be in the best position to advise you on these questions.

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

Kind regards,

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From: [redacted]
Sent: Wednesday, September 24, 2014 10:48 AM
To: OC GCP Questions; CDER DRUG INFO
Subject: Question on submission of investigator information to FDA for IND protocol investigators, domestic and foreign

I wanted to request some further insights on the FDA regulation below excerpted from 312.23(a)(6)(iii)(b)

> (6)(iii) A protocol is required to contain the following, with the specific elements and detail of the protocol reflecting the above distinctions depending on the phase of study:
>
> (*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.

QUESTIONS:
1- How frequently does FDA want IND protocol amendment updates for new investigators?
2- What would qualify as an **'other statement of qualifications'**. CVs can sometimes be over 50 pages. Would name and position title for the investigator be sufficient?
3- If the sponsor maintains the signed 1572s and CVs, etc does the FDA accept a spreadsheet to fulfill this regulation about investigator information if the spreadsheet contains the name, address, title/position of the investigator, sub-investigators, research facility name and address, IRB name and address?
4- Does FDA have any recommended approaches to simplifying these submissions for phase 3 studies with 100+ investigator sites?

Thank you

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