From: OC GCP Questions
To: [redacted]
Subject: RE: IRB Review of Sub-Investigators
Date: Tuesday, January 19, 2016 4:34:00 PM
Attachments: [redacted]

Dear [redacted] -

Thank you for your question. The regulations at 21 CFR 56.108(a)(1) require IRBs, among other things, to follow written procedures for conducting its initial and continuing review. These regulations state:

> Sec. 56.108 IRB functions and operations.
>
> In order to fulfill the requirements of these regulations, each IRB shall:
>
> (a) Follow written procedures: (1) For conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution;

The IRB regulations at 21 CFR 56 do not specifically address your question about whether or not the IRB is required to review subinvestigator information such as a CV and licensure because the regulations are not that prescriptive. The regulations provide IRBs the flexibility to establish written procedures best suited to their own operations. When the regulations are silent, IRBs, institutions, sponsors, and investigators are free to develop their own procedures and practices as long as applicable regulatory requirements are met.

The ICH GCP E6 Good Clinical Practice: Consolidated Guidance, (which is recognized as official FDA guidance –see http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073122.pdf) addresses IRB responsibilities in section 3.1. Section 3.1.2 reads:

> 3.1.2 The IRB/IEC should obtain the following documents:
>
> Trial protocol(s)/amendment(s), written informed consent form(s) and consent form updates that the investigator proposes for use in the trial, subject recruitment procedures (e.g., advertisements), written information to be provided to subjects, Investigator's Brochure (IB), available safety information, information about payments and compensation available to subjects, the investigator's current curriculum vitae and/or other documentation evidencing qualifications, **and any other documents that the IRB/IEC may require to fulfil its responsibilities. [emphasis added]**

FDA also has guidance titled, "*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*" which can be found at http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM328855.pdf. You may find this guidance helpful in assessing your IRB's written procedures.

FDA also has guidance titled, "*Investigator Responsibilities - Protecting the Rights, Safety, and Welfare of Study Subjects*" (see http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm187772.pdf) that may also be of interest to you.

I hope this information is useful. If you need further information and/or have additional questions, please feel free to contact us at the official GCP mailbox, gcp.questions@fda.hhs.gov. You may also find it useful to access the set of redacted GCP e-mails found at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGoodClinicalPractice/default.htm since we find that many questions and concerns are repeated over time.

Best Regards,

Janet

Janet Donnelly, RAC, CIP
Policy Analyst, Office of Good Clinical Practice
Office of Special Medical Programs, Food and Drug Administration

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.

From: [redacted]
Sent: Thursday, January 14, 2016 10:20 AM
To: OC GCP Questions
Subject: IRB Review of Sub-Investigators

Good Morning,

Per our policy, the IRB reviews sub-investigators only when they are performing procedures that the principal investigator is not qualified though expertise to perform. Does the FDA require the IRB to review sub-investigator information (CV/licenses) for all the sub-investigators?

[redacted] holds the PI responsible for selecting adequate sub-investigators to assist in the conduct of the research study.

Your guidance is greatly appreciated.

Thank you in advance,

[redacted]