From: OC GCP Questions
To: [redacted]
Subject: Sub-I / Back-up PI Requirement
Date: Friday, May 15, 2015 12:35:58 PM

Good morning –

Thank you for your question. While not a regulatory requirement most clinical study sites do have sub-investigators. The requirement that the sub-CI have the same credentials as the PI would be up to the sponsor and state and local laws governing licensing. The investigator (also referred to as the principal investigator or PI) is responsible for supervising the conduct of the clinical investigation and to protect the rights, safety, and welfare of participants in drug and medical device clinical trials. PI's commit themselves to personally conduct or supervise the investigation. It is common practice for investigators to delegate certain study-related tasks to employees (including the sub-CI), colleagues, or other third parties, but the investigator remains responsible for providing adequate supervision of those to whom tasks are delegated. Essentially, the PI may delegate tasks on a given study, but they may not delegate their role or responsibilities as PI.

FDA encourages each study site to have their own CI, who signs a 1572, for the conduct of the study at the specific site. Sub-investigators are intended to assist the CI conduct the study at a specific site and not to substitute for the CI. The intention of FDA regulations are for the CI to conduct and/or supervise all aspects of a clinical study for which he/she agrees to conduct, according the investigational plan and applicable regulations, when he/she signs the 1572.

FDA's definition of investigator is found at 21 CFR 312.3:

Investigator means an individual who actually conducts a clinical investigation (i.e., under whose immediate direction the drug is administered or dispensed to a subject). In the event an investigation is conducted by a team of individuals, the investigator is the responsible leader of the team. "Subinvestigator" includes any other individual member of that team.

FDA has a guidance document for industry titled, "Investigator Responsibilities - Protecting the Rights, Safety, and Welfare of Study Subjects" that can be found at http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm187772.pdf . This guidance was developed to clarify for investigators and sponsors FDA's expectations concerning the investigator's responsibility (1) to supervise a clinical study in which some study tasks are delegated to employees or colleagues of the investigator or other third parties and (2) to protect the rights, safety, and welfare of study subjects.

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

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Tuesday, May 12, 2015 12:45 PM
To: OC GCP Questions
Subject: Sub-I / Back-up PI Requirement

Hello,

Is there any guidance or regulatory requirement for a clinical site to have a backup for the PI, with same/similar credentials to take over if needed?

Thank you,

[redacted]