From: OC GCP Questions
To: [redacted]
Subject: PI or SI Signature on Protocol?
Date: Monday, November 16, 2015 10:44:54 AM

Good morning –

The short answer is yes. However, I can offer you the following information --

In accordance with FDA's regulations, investigators are required to commit to personally conduct or supervise the investigation (for drug and biologic studies under 21 CFR 312.53(c)) or to supervise all testing (for medical device studies under 21 CFR 812.43(c)).

The idea of delegation of authority appears in some FDA guidance documents. For example, the ICH E6 Good Clinical Practice: Consolidated Guidance (which is recognized as official FDA guidance – see http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073122.pdf) states in section 4.1.5:

4.1.5 The investigator should maintain a list of appropriately qualified persons to whom the investigator has delegated significant trial-related duties.

The ICH E6 GCP guidance also mentions having a signature sheet on file to document signatures and initials of all persons authorized to make entries and/or corrections on CRFs (see section 8.3.24).

Another FDA 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), discusses a clinical investigator's responsibilities when delegating study tasks. This guidance refers back to section 4.1.5 of the ICH E6 guidance on page 3 and includes the following statement:

The investigator should maintain a list of the appropriately qualified persons to whom significant trial-related duties have been delegated. This list should also describe the delegated tasks, identify the training that individuals have received that qualifies them to perform delegated tasks (e.g., can refer to an individual's CV on file), and identify the dates of involvement in the study. An investigator should maintain separate lists for each study conducted by the investigator.

We are aware that delegation of study tasks is typically done on a study-by-study basis as each study may have unique study requirements that require careful consideration by the PI in determining what, if any tasks can be delegated, and to whom. I recommend that even if you have an SOP that outlines delegation responsibilities that you ensure there is a mechanism by which the PI carefully considers each study and the unique aspects of the tasks required by each study. Additionally FDA would expect study staff to follow state and local laws regarding medical licensure and medical practice requirements in addition to sponsor requirements.

Because sponsors and sites have the flexibility to adopt procedures that make the most sense to them and their existing business practices, I recommend you discuss how to address this issue with the appropriate intuitional officials at your site, and then further discuss it with the appropriate representatives at the sponsor company.

I hope this information is helpful. Please contact us again at 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

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: Friday, November 13, 2015 12:16 PM
To: OC GCP Questions
Subject: PI or SI Signature on Protocol?

Hello,
At an investigator site, could you tell me if a Sub-investigator may sign a protocol or protocol amendment in the absence of the Principal Investigator? Is this a responsibility that may be delegated by the PI?
Thank you in advance.

[redacted]