From: OC GCP Questions
To: [redacted]
Subject: Principal Investigator Question
Date: Tuesday, March 13, 2018 12:09:00 PM
Attachments: [redacted]

Good afternoon –

There is no set percentage in FDA regulations that points to adequate supervision of an FDA-regulated clinical trial. 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, 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.

You may wish to review FDA's guidance document -Investigator Responsibilities -Protecting the Rights, Safety, and Welfare of Study Subjects www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf.

Section III.A.3. of this guidance says:

3. What Is Adequate Supervision of the Conduct of an Ongoing Clinical Trial?

For each study site, there should be a distinct individual identified as an investigator who has supervisory responsibility for the site. Where there is a subinvestigator at a site, that individual should report directly to the investigator for the site (i.e., the investigator should have clear responsibility for evaluating the subinvestigator's performance and the authority to terminate the subinvestigator's involvement with the study) and the subinvestigator should not be delegated the primary supervisory responsibility for the site.

In assessing the adequacy of supervision by an investigator, FDA focuses on four major areas: (1) whether individuals who were delegated tasks were qualified to perform such tasks, (2) whether study staff received adequate training on how to conduct the delegated tasks and were provided with an adequate understanding of the study, (3) whether there was adequate supervision and involvement in the ongoing conduct of the study, and (4) whether there was adequate supervision or oversight of any third parties involved in the conduct of a study to the extent such supervision or oversight was reasonably possible.

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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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: Monday, March 12, 2018 1:49 PM
To: OC GCP Questions <gcp.questions@fda.hhs.gov>
Subject: Principal Investigator Question

Should a PI only delegate only 20 percent of their time to a clinical trial or are there exceptions?