From: OC GCP Questions
To: [redacted]
Subject: PI Issue
Date: Wednesday, September 09, 2015 1:11:40 PM

Good afternoon –

I cannot advise you on legal issues as I am not an attorney.

The regulations are very broad when it coming to supervising an FDA-regulated clinical trial. The regulations require that sponsors choose investigators qualified by training and experience (see 21 CFR 312.53(a)). The regulations also require that investigators commit themselves to personally conduct or supervise the investigation (see 21 CFR 312.53(c)(1)(vi)(c)).

Training, education, and experience required for sponsor personnel may necessarily, and appropriately, vary depending on the type of product, the indication, the study being conducted, and its associated risk. FDA's regulations are not explicit as to what constitutes adequate training, education and experience, nor do they outline specific qualifications, including whether such personnel must hold an active medical license. Moreover, sponsors have discretion in determining what qualifications are needed in certain positions based on the general recognition that this would include education, training and experience pertinent to the particular clinical study and its design and execution, as well as familiarity with human subject protection (HSP) regulations, recordkeeping, data integrity, and good clinical practice (GCP) standards and requirements.

FDA would expect physicians and study staff to follow state and local laws regarding medical licensure and medical practice requirements in addition to sponsor requirements.

If the new clinical investigator (PI) is selected, this individual would need to sign a new 1572. Additionally, I strongly advise that you consult the FDA regulatory project manager (RPM) of the IND/IDE to discuss this situation with them. The sponsor should have the RPM's contact information.

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
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Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Wednesday, September 09, 2015 11:36 AM
To: OC GCP Questions
Subject: PI Issue

Good Morning!

First let me outline the situation and then pose our question.

We have 12 studies in a specialty with a physician who was first put on two week administrative leave, and has now decided to leave the practice. There is no other physician in said practice that would take on the studies. We have a currently licensed physician, in good standing, and, in that specialty, who would agree to assume PI status, but is not affiliated with a hospital or office. He has retired from practice, but would see subjects in our research clinic and refer issues back to the subjects primary care physician.

Would this be acceptable legally, with the Sponsors permission and what would be FDA guidance?

We have several subjects who are doing well within these protocols and want to do what is best for them. Thank you for your answer in advance.

[redacted]