From: OC GCP Questions
To: [redacted]
Subject: Question avout physician investigator
Date: Friday, January 23, 2015 11:10:03 AM

Good morning --

I am sorry I don't think I can specifically give advice on your situation. That said, I can offer the following information. FDA's expectation is that clinical investigators (CI), sub-investigators, and study staff will be knowledgeable about good clinical practice, including human subject protection, data integrity, recordkeeping, etc. Note that sponsors have discretion in determining what qualifications will be needed to conduct a study and may identify in the protocol a required frequency of GCP training, in which case the investigator and sub-investigators would be expected to meet that frequency of training in order to comply with the sponsors requirements. Every effort should be made to train the investigational sites.

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)).

It might be helpful for you to review FDA's guidance on Investigator Responsibilities - Protecting the Rights, Safety, and Welfare of Study Subjects (available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf)

Additionally, FDA would expect physicians who are clinical investigators follow state and local laws regarding medical licensure and medical practice requirements in addition to sponsor requirements.

Some sponsors will check a clinical investigator's past regulatory history for compliance with FDA regulations in FDA-regulated clinical trials. You can search FDA's Warning Letter website for clinical investigator non-compliance. Please see the web link below.

Warning Letters

Please also see FDA links below to clinical investigator inspections and CI compliance manual.
http://www.fda.gov/downloads/ICECI/EnforcementActions/BioresearchMonitoring/UCM133773.pdf

http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126553.pdf

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: Thursday, January 22, 2015 5:35 PM

To: OC GCP Questions
Subject: Question avout physician investigator

Good Afternoon:

I was hoping you could give me some guidance with a scenario that I am deliberating over. I have an excellent physician who has worked with us on some internal medicine (diabetes, cholesterol and asthma not on any other aspects of his practicing medicine) clinical trials and he has been issued a probation on his license for one year specifically for the management of chronic pain patients. He is still allowed to treat acute pain and can continue to prescribe opioids for this.

In short, the reason for the probation is because he had a couple of patients that the Board felt he should have referred out to specialist for their pain management because they were on higher doses of opioids and they didn't feel his records reflected enough background for him to treat them in this way. He did appeal to the Board initially because he didn't agree with their assessment but lawyers fees etc were so high that he made a settlement of the one year probation instead of going through the whole process. He no longer treats chronic pain patients which only made up a very small percentage of his population.

My question is: Should I not be using him as a Principal Investigator for my studies because of this issue?
He has been an excellent PI for us who really understands what is required of him in his role as PI and conducts the studies accordingly, **but I didn't know how the FDA views this situation.** The probation ends in May but even so this is on his "record" I would imagine. For current studies, we have informed the Sponsors and IRB and it has not been an issue except for one who was uncomfortable about this but was OK since he was a Sub-I and not the PI. What would the FDA opinion on this be?

Your guidance would be very helpful.

Thank you,

[redacted]