From: OC GCP Questions
To: [redacted]
Subject: Research questions concerning Principal Investigator hiring/selection
Date: Friday, January 09, 2015 1:14:18 PM

Good afternoon --

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

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, January 09, 2015 10:20 AM
To: OC GCP Questions

Subject: Research questions concerning Principal Investigator hiring/selection

Hello Sir/Madam,

My name is [redacted] and I am an occupational/rehabilitation consultant working for [redacted] corporation. I do a great deal of vocational work with physicians and dentists. Based on my research into the FDA, I am hoping you might be able to assist me on a few questions I have in regards to the role, selection, eligibility and eventual hiring of Principal Investigators to complete clinical pharmaceutical drug trials.

For example,

1. What are the key factors that the FDA and/or a sponsoring pharmaceutical company looks for when seeking out a Primary Investigator to head up a particular clinical drug trial?

2. What skills, traits, temperaments, expertise, or employment traits would be considered most attractive?

3. What skills, traits, temperaments, expertise, or employment traits would render a physician unsuitable in exploring the employment role of a Principal Investigator?

As an FYI, I have reviewed the two excellent Guidance Manuals produced by the FDA and GCP in reference to *Investigators Responsibilities-Protecting the Rights, Safety, & Welfare of Study Subjects* and *Financial Disclosures by Clinical Investigators*.

However, any further expertise you wish to share in regards to the above three questions would be most helpful.

Thank you and have a nice day.

[redacted]