From: OC GCP Questions
To: [redacted]
Subject: GCP training question
Date: Monday, March 31, 2014 12:28:34 PM

Good afternoon:

Neither FDA's regulations nor guidance provide guidelines on how often GCP training should be completed and by whom and who can perform the training. FDA does not require or provide certification. This would be up to the sponsor. 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)). 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) states that, "The investigator should ensure that any individual to whom a task is delegated is qualified by education, training, and experience (and state licensure where relevant) to perform the delegated task."

The expectation is that investigators, 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.

Additionally, FDA does have information about available GCP training on the GCP website, specifically at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/EducationalMaterials/ucm112925.htm

Both the Center for Drug Evaluation (CDER) and the Center for Devices and Radiological Health (CDRH) provide online training relevant to clinical trials on their respective websites. These training programs are accessible at CDER Learn http://www.fda.gov/Training/ForHealthProfessionals/default.htm and CDRH (Center for Devices) Learn http:///www.fda.gov/Training/CDRHLearn/default.htm respectively.

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, March 28, 2014 10:14 AM
To: OC GCP Questions
Subject: GCP training question

Dear FDA GCP Team,

I was under the impression that Principal Investigators conducting clinical trials are required to complete

a GCP training course (e.g. CITI course) and obtain certification in order to be compliant with conducting clinical research. However, I have also been informed by colleagues that there is not necessarily a "regulatory requirement" to be GCP trained, as long as the PI is in compliance with the study's protocol and IB, and following the applicable SOPs (site's SOPs, sponsor's SOPs, CRO's SOPs, etc), and GCPs are thought of more as simply "guidelines".

Is it required by the FDA that the PI (as well as any personnel conducting clinical research, for that matter) attend GCP training and obtain documentation/certification of completion of training to conduct clinical research? And if so, how often (just once for life, every year, every 2 years, etc)?

Please let me know if you have any questions.

Thank you very much for your time and any feedback you can provide.

Kind regards,

[Redacted]