From: OC GCP Questions
To: [redacted]
Subject: Question - documentation of protocol specific training
Date: Thursday, July 10, 2014 10:07:30 AM

Good morning –

FDA regulations pertaining to recordkeeping practices for clinical trial records are fairly general including documentation of protocol training. The regulations do not specifically address how documentation should be performed. However it should be detailed enough so that if an FDA inspection should occur, the investigator can follow an adequate audit trail. Since the FDA regulations on recordkeeping practices are general, sites therefore have flexibility in how they handle documents at their sites because FDA's regulations do not specify how this must be done. I also recommend that you have a standard operating procedure in place to address this issue. When FDA regulations are silent, institutions are free to develop their own standard operating procedures (SOPs) or policies to address specific situations. While not mandatory, SOPs provide a standard working tool that can be used to document routine quality system management and technical activities. SOPs provide consistency when a process is being performed. They reduce the chance of errors and provide guidelines for employees to follow

Additionally, neither FDA's regulations nor guidance provide specific guidelines on how often GCP training should be completed by principal and sub-investigators and study staff involved in investigational drug research. 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 and 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 and well as documentation of training, in which case the investigator and sub-investigators and study staff would be expected to meet that frequency of training in order to comply with the sponsors requirements. What training is needed and how it is documented depends to some degree on the nature of the study. Some protocols need extensive training and others may need minimal, also dependent upon the background and experience of study staff. If you are looking at standardizing your process, I will assume you are planning to write SOPs in this regard or something relatively akin to such. Therefore, you should decide what will work best for your site under a variety of possible scenarios and then make sure that these are followed.

The link below takes you to FDA's Compliance Program for clinical investigators. You will find helpful information as to what occurs during a FDA inspection.

http://www.fda.gov/downloads/ICECI/EnforcementActions/BioresearchMonitoring/UCM133773.pdf

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

From: [Redacted]
Sent: Wednesday, July 09, 2014 3:59 PM

To: OC GCP Questions
Subject: Question - documentation of protocol specific training

Dear,

I would like to ask for clarification regarding the expectations regarding protocol/project specific training.

I would like to give you the following cases:

- Does a monitor need to document training of the monitoring guidelines.
- Does a statistician need to document protocol training if he was one of the protocol reviewers/writers
- Does a statistician reviewing the statistical analysis plan need to document training of the protocol
- Does a statistician creating the statistical program need to document training of the statistical analysis plan
- Does a data manager need to document training of the data management plan
- Which functions are required to be trained on the protocol, is protocol training expected for somebody doing data entry, do you in this case expect training of data entry guidelines?

Many thanks in advance for your response.

Kind regards,

[Redacted]