From: OC GCP Questions
To: [redacted]
Subject: Protocol Training Documentation
Date: Tuesday, April 15, 2014 9:09:49 AM

Good morning –

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 or how the training should be documented. 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)).

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.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

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Senior Health Policy Analyst
Office of Good Clinical Practice
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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: Tuesday, April 15, 2014 7:55 AM
To: OC GCP Questions
Subject: Protocol Training Documentation

Good Morning,

I have a question in regards to the FDA's expectations when it comes to the documentation of protocol specific training for study team members. Per 21 CFR 312.53 (c) (vi*) commitment by the investigator (g) will ensure that all associates, colleagues, and employees assisting in the conduct of the study (ies) are informed….* Would the FDA require documentation that each study team member has received **AND** reviewed the information? We are trying to develop a policy that is in compliance with the regulations and FDA's expectations in regards to the documentation of training. Thank you so much for any insight you can provide! ώwŜŘł·ŎűŜŘϐ