

From: Brown, Sheila (OGCP)
To: [REDACTED]
Subject: RE: GCP Training
Date: Monday, July 20, 2015 2:04:00 PM

Dear [REDACTED],

FDA does not have a preference for GCP training for investigators; it depends on the sponsor recommendations. The expectation is that investigators and sub-investigators will be knowledgeable about good clinical practice, including human subject protection, data integrity, recordkeeping, etc. As noted, the 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. This is the sponsor's responsibility.

Neither FDA's regulations nor guidance provide guidelines on how often GCP training should be completed by principal and sub-investigators involved in investigational drug or device research. The regulations require that sponsors choose investigators qualified by training and experience (see 21 CFR 312.53(a) and 21 CFR 812.43(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) and 21 CFR 812.43(c)(4)). 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 CPGM for FDA inspection of Sponsors, Contract Research Organizations and Monitors can be found at:

<http://www.fda.gov/ICECI/EnforcementActions/BioresearchMonitoring/ucm133777.htm>

Please see information link below on GCP training.
Educational Materials > Does FDA Conduct GCP Training?

ICH-E6 on Good Clinical Practice has information on training and monitoring that would be helpful to you.
<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf>

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

Best regards,

Sheila

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This communication does not constitute a written advisory opinion under Title 21 CFR 10.85, but rather is an informal communication under Title 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: Monday, July 20, 2015 9:38 AM

To: OC GCP Questions

Subject: GCP Training

As a general question regarding GCP training for investigators: In an audit, would the FDA consider that either NIH or CITI GCP training is acceptable as far as ~~CYXUMX~~ clinical trials are concerned?

Thank you for your time and attention.

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