**From:** OC GCP Questions
**To:** [redacted]
**Subject:** Question regarding GCP training for Investigators
**Date:** Friday, January 10, 2014 10:11:21 AM

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Good morning –

FDA does not have a preference. 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 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 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.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA



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**From:** [Redacted]

**Sent:** Thursday, January 09, 2014 4:18 PM
**To:** OC GCP Questions
**Subject:** Question regarding GCP training for Investigators

Can you please advise if it is preferable for Investigators to have NIH Certification or CITI training certificate?

[Redacted]