

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: GCP Training Documentation
Date: Wednesday, September 23, 2015 6:16:53 AM

Good morning --

Please see the information below regarding GCP training.

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.

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

Kind regards,

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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, September 22, 2015 4:51 PM
To: OC GCP Questions
Cc: [REDACTED]
Subject: GCP Training Documentation

Good day FDA Office of GCP Compliance:

What is the FDA regulations or guidance on clinical site study staff having GCP training documentation prior to study start up before engaging in the conduct of a clinical research study? Is the GCP training requirement applicable for the principal investigator and/or sub-investigators at the clinical investigative site, only. Are their staff such as study coordinators, pharmacy personnel, and other study site staff with minimal responsibility (blood draw technicians) exempt from GCP training? I realize 21 CFR 312.55 and 21 CFR 812.55 do not address this question [from my interpretation of the regulation because it relates to the sponsor providing the investigators an Investigator Brochure (IB)] and new observations related up update the IB. According to 21 CFR 312.53, the sponsor must select investigators qualified by training and experience and to commit themselves to personal conduct, provide sufficient oversight and supervision of the investigation and their study site staff

involved in the conduct of the investigational drug research. These individuals who are delegated protocol specific tasks must be qualified by education, training, and experience, which may include having a professional license and perhaps certification to perform delegated task authorized by the principal investigator. The entire clinical site team must be knowledgeable [not just aware of] good clinical practice, human subject protection, good documentation practice to ensure data integrity, how to handle, store, and administer the investigator product, etc. Where in the regulations or FDA guidance document is it written that investigators and their study site staff must have GCP training? I understand such training helps to document the qualification, knowledge, and experience of investigators and their study site staff AND must GCP training be documented prior to conducting any study activities? Please provide to me a response. Note: I visited the FDA website at www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/EducationalMaterials/ucm112925.htm

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Respectfully,

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