

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: GCP Training, non-PI Site personnel
Date: Thursday, June 25, 2020 1:52:47 PM
Attachments: [REDACTED]

Good afternoon –

A lot of sponsor training is study-specific. In those cases where sponsor training is to ensure general GCP knowledge as well, a university/research establishment or training facility can discuss their training with the sponsor when approached as a potential site for a specific study and negotiate as to the time and effort spent with sponsor training beyond that which is study-specific.

Below is general information on GCP training.

Neither FDA's regulations nor guidance provide guidelines on how often GCP training and/or retraining should be completed and by whom and who can perform the training. Also, FDA does not require or provide certification. This would be up to the sponsor and the sponsor would also be involved in the documentation of training, if needed. 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 - <https://www.fda.gov/media/77765/download> 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."

FDA regulations regarding qualifications for those involved with the conduct of clinical studies are very broad. Both Title 21, Code of Federal Regulations (21 CFR) Part 312 (for drugs and biologics) and 812 (for medical devices) simply state that sponsors are required to choose clinical investigators and study staff that are qualified by training and experience. Logically, clinical investigators and study staff need to be knowledgeable about applicable regulations as well as specific areas essential to the conduct of the particular study.

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. 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. Whether to retrain the study staff would be the sponsor's responsibility.

Additionally, 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. However, the sponsor and your internal SOPs should address this issue.

Also please see FDA's guidance on monitoring <https://www.fda.gov/media/121479/download>

Kind regards,

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From: [REDACTED]
Sent: Thursday, June 25, 2020 10:52 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: GCP Training, non-PI Site personnel

Good day,

I was curious if there is current FDA policy or guidance on whether those performing study-specific procedures outside of the PI institution, such as a radiology clinic to perform protocol MRI's, are required to complete GCP training if what that facility is performing is no different than what that the would do on a daily, standard-of-care basis. I understand that such facilities would most likely be following a study protocol or data collection/imaging manual to complete their tasks, but the tasks themselves do not represent new, novel, or experimental methods of collecting data.

I see some guidance from the National Institute for Allergy and Infectious Disease <https://www.niaid.nih.gov/research/human-subject-protection-good-clinical-practice-training> from which I would like to know the FDA's current thoughts regarding how much *PI discretion* weighs on which personnel should actually be GCP trained based on their level of research involvement (again, the example of a technician performing routine, standard-of-care procedures).

Thank you for your time and feedback.



