

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: GCP training requirements
Date: Thursday, December 17, 2015 1:12:40 PM

Good afternoon –

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.

The sponsor should determine if those individuals listed in your email should receive training for a specific clinical study.

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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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: Thursday, December 17, 2015 12:21 PM
To: OC GCP Questions
Subject: GCP training requirements

Hello: Are there any guidelines or regulations about who beyond the PI, Sub I and study coordinator should have GCP training? I have been unable to get a clear answer about this.

Specifically: should the following staff be required to complete GCP training?:

- nurses who administer study medications
- nurses in the outpatient clinics who perform study related vital signs
- Phlebotomists who draw blood for research samples
- Lab techs who process and ship research samples
- EKG techs or any other tech who performs a study related test or procedure

Thank you so much for you time!

