

From: [OC GCP Questions](#)
To: [REDACTED]
Cc:
Subject: Seeking Clarification on research staff training requirements - Investigator responsibilities.
Date: Wednesday, December 09, 2015 10:08:40 AM

Good morning –

Your email was forwarded to my office for a response.

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.

FDA regulations pertaining to recordkeeping practices (specifically training documentation) for clinical trial records are fairly general. The regulations do not specifically address how documentation should be performed. However it should be detailed enough so that if an FDA inspection should occur, the investigator can follow an adequate audit trail. Since the FDA regulations on recordkeeping practices are general, sites therefore have flexibility in how they handle documents at their sites because FDA's regulations do not specify how this must be done. I also recommend that you have a standard operating procedure in place to address this issue. When FDA regulations are silent, institutions are free to develop their own standard operating procedures (SOPs) or policies to address specific situations. While not mandatory, SOPs provide a standard working tool that can be used to document routine quality system management and technical activities. SOPs provide consistency when a process is being performed. They reduce the chance of errors and provide guidelines for employees to follow

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
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Office of Good Clinical Practice
Office of the Commissioner, FDA

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: Friday, December 04, 2015 3:08 PM

To: CDER DRUG INFO

Subject: Seeking Clarification on research staff training requirements - Investigator responsibilities.

Good afternoon.

I'm hoping that someone can provide some additional clarification on what is expected for training of research study staff on protocols and very specifically on protocol updates when they occur.

The language below from the guidance linked states that the PI needs to ensure that staff have "adequate understanding" of the protocol.

This is somewhat difficult to qualify. How can we say if a person does or does not have understanding? We provide everyone with updates to protocols, digests of the relevant changes, etc. But does providing information equate to "ensuring" understanding? For example: Does a person need to acknowledge that they have read and understood the updates in order to show "adequate understanding"?

Do you have any clear expectations/suggestions of how a site should document ongoing training with regards to protocol updates? Obviously, the larger the group the more complex and cumbersome the process the more time will need to be spent on this. Therefore if there is any specific expectation/requirement for such documentation, we would like to know what that would be to ensure our compliance.

Would appreciate any advice or suggestions on how best to comply with expectations and document this adequately.

Thank you very much,

[REDACTED]

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf>

2. What Is Adequate Training?

The investigator should ensure that there is adequate training for all staff participating in the conduct of the study, including any new staff hired after the study has begun to meet unanticipated workload or to replace staff who have left. The investigator should ensure that staff:

- Are familiar with the purpose of the study and the protocol
- Have an adequate understanding of the specific details of the protocol and attributes of the investigational product needed to perform their assigned tasks
- Are aware of regulatory requirements and acceptable standards for the conduct of clinical trials and the protection of human subjects

- Are competent to perform or have been trained to perform the tasks they are delegated
- Are informed of any pertinent changes during the conduct of the trial and receive additional training as appropriate.

If the sponsor provides training for investigators in the conduct of the study, the investigator should ensure that staff receive the sponsor's training, or any information (e.g., training materials) from that training that is pertinent to the staff's role in the study.