

From: [OC GCP Questions](#)
To: [Redacted]
Subject: GCP Training for IND Trial
Date: Thursday, July 10, 2014 9:46:13 AM

Good morning --

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.

Additionally, FDA does have information about available GCP training on the GCP website, specifically at <http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/EducationalMaterials/ucm112925.htm>

Both the Center for Drug Evaluation (CDER) and the Center for Devices and Radiological Health (CDRH) provide online training relevant to clinical trials on their respective websites. These training programs are accessible at CDER Learn <http://www.fda.gov/Training/ForHealthProfessionals/default.htm> and CDRH (Center for Devices) Learn <http://www.fda.gov/Training/CDRHLearn/default.htm> respectively.

As to the individuals that you list in your email, the sponsor would have to determine if GCP training is needed based on their involvement in the 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,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
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: Wednesday, July 09, 2014 11:50 AM
To: OC GCP Questions
Subject: GCP Training for IND Trial

Dear OGCP Representative,

As a past monitor of IND trials and a new research manager of IND trials, I want to ensure I understand fully the GCP training requirements for our study team members. My questions:

1. It's clear that all staff who work on a trial, whether key personnel or part-time temporary undergraduate clerical staff, must receive human subjects training before commencing trial activities. However, where does one draw the line with regard to GCP training?
 - a. Part-time undergraduate students who have no patient contact?
 - b. Part-time undergraduate students who assist with patient visits in a minimal way?
 - c. Research nurses at a clinical research unit that is used only to draw blood (i.e. study coordinators who are GCP trained are present)?
 - d. Other guidance you can provide?
2. How often is GCP training required?

Thank you for any guidance you provide.

[Redacted]