From: OC GCP Questions
To: [redacted]
Subject: Good Clinical Practice Education
Date: Wednesday, January 15, 2014 7:09:48 AM

Good morning:
Neither FDA's regulations nor guidance provide guidelines on how often GCP training should be completed by principal, sub-investigators and study staff involved in investigational drug research. 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 Learn http:///www.fda.gov/Training/CDRHLearn/default.htm respectively.

Please see information link below on GCP training.
Educational Materials > Does FDA Conduct GCP Training?

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
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From: [Redacted]
Sent: Tuesday, January 14, 2014 1:37 PM
To: OC GCP Questions
Subject: Good Clinical Practice Education

I would like to find out what the FDA guidance is on proof of GCP training for research staff. Sponsors are

asking sites more and more for proof of GCP training, my question is how often does GCP training need to occur? Is a onetime training Certificate sufficient or is the FDA guidance more of a renewal of GCP biannually? I would appreciate any feedback or directions you could provide.

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