From: OC GCP Questions
To: [redacted]
Subject: Electronic Training Records
Date: Thursday, October 02, 2014 11:29:15 AM

Good morning --

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.

The expectation is that investigators and sub-investigators 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.

If the electronic record is required by FDA regulations, and not subject to the enforcement discretion exceptions in the Scope and Application guidance, Part 11 controls are necessary.

Please see:
Part 11, Electronic Records; Electronic Signatures — Scope and Application
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm072322.pdf

For general information on the use of computer systems in clinical trials in FDA regulated clinical trials, please reference the following guidance:

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070266.pdf

Electronic Source Data in Clinical Investigations:

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM328691.pdf

I hope this information is helpful. Please contact us again at gcp.quesstions@fda.hhs.gov should you have additional questions.

Kind regards

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Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Wednesday, October 01, 2014 1:44 PM
To: OC GCP Questions
Subject: Electronic Training Records

Hello,

Are electronic training records for individuals conducting clinical research required to follow Part 11 requirements?

Thank you.

[redacted]