From: OC GCP Questions
To: [redacted]
Subject: Electronic Records; Electronic Signatures (21 CFR Part 11)
Date: Friday, July 11, 2014 2:44:46 PM

Good afternoon,

An electronic data capture system for FDA-regulated studies should be Part 11 compliant. FDA's regulations for electronic records and electronic signature can be found at 21 CFR Part 11 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=11). Part 11 applies to records in electronic form that are created, modified, maintained, archived, retrieved, or transmitted under any records requirements set forth in Agency regulations, as well as electronic records submitted to the Agency under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, even if such records are not specifically identified in Agency regulations.

I've listed below a few FDA guidance documents that you may find helpful:

FDA's Guidance for Industry – Computerized Systems Used in Clinical Investigations found at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070266.pdf

FDA's Draft Guidance for Industry – Electronic Source Data in Clinical Investigations found at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM328691.pdf

FDA's Guidance for Industry -- Part 11, Electronic Records; Electronic Signatures --Scope and Application found at http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126953.pdf

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

From: [Redacted]
Sent: Thursday, July 10, 2014 3:20 PM
To: OC GCP Questions
Subject: RE: Electronic Records; Electronic Signatures (21 CFR Part 11)

Hello,

Does an electronic data capture system have to be 21 CFR part 11 compliant when doing human subject clinical research? If not, what are the variables to take in to account when determining

whether or not it should be?

Thank you,
[Redacted]