From: OC GCP Questions
Sent: Friday, March 21, 2014 10:06 AM
To:
Subject: DrugInfo Comment Form FDA/CDER Site

Good morning,

Your email was forward to my office for a response. I might suggest that you review a new FDA guidance related to electronic source data which may help with your question (http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm328691.pdf). This document includes information related to the creation and maintenance of electronic case report forms(eCRF). It describes and electronic medical record (EMR) as a possible data originator for an eCRF. However, section IV. of the document states that, although adequate controls need to be in place to ensure confidence in the reliability, quality and integrity of electronic source data, performance standards for EMRs may be regulated by other authorities and FDA does not intend to assess compliance of EMRs with part 11.

Other guidances that might be helpful to you are listed below.

Computerized Systems Used in Clinical Investigations:
www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070266.pdf

Part 11, Electronic Records; Electronic Signatures--Scope and Application:
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.

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

-----Original Message-----
From: druginfo@fda.hhs.gov [mailto:druginfo@fda.hhs.gov]
Sent: Tuesday, March 18, 2014 8:21 PM
To: CDER DRUG INFO
Subject: DrugInfo Comment Form FDA/CDER Site

Name: [Redacted]

E-Mail: [redacted]

Comments: Are hospital eMRs required to be compliant with 21 CFR Part 11? Is a research site conducting research under a pharmaceutical sponsor's FDA-approved protocol required to verify that the site's electronic systems are 21 CFR 11 compliant?

URL: http://www.fda.gov/regulatoryinformation/guidances/ucm125067.htm