From: OC GCP Questions
To: [redacted]
Subject: Part 11 and Sponsor-Investigator Trials
Date: Monday, May 11, 2015 10:56:38 AM

Good morning –

Any electronic records in a FDA-regulated clinical trial (sponsor only or sponsor-investigator) should be Part 11 compliant except EMRs.

The guidances listed below might be helpful to you.

Part 11 –Electronic Records --
http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126953.pdf

Computerized Systems Used in Clinical Investigations –
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
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.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov for 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: Friday, May 08, 2015 4:32 PM
To: OC GCP Questions
Subject: Part 11 and Sponsor-Investigator Trials

Dear FDA,

Do you expect sponsor investigators to adhere to part 11 compliance with regard to the management of their multi-site studies?

Sincerely,

[redacted]