From: OC GCP Questions
To: [redacted]
Subject: GCP question about 21 CFR Part 11
Date: Thursday, September 10, 2015 6:56:35 AM

Good morning –

Electronic records in a FDA-regulated clinical trial that will be submitted in a marketing application to the agency 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.

Additionally since you mention medical devices in your email, you might also want to check with the Center for Devices (CDRH) at DICE@fda.hhs.gov.

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: Wednesday, September 09, 2015 4:41 PM
To: OC GCP Questions
Subject: GCP question about 21 CFR Part 11

To whom it may concern,

I have a question regarding 21 CFR Part 11. We often conduct sponsored clinical studies that involve

commercially available medical devices (used as per label) and where performance data for example are used for marketing purposes. We often also conduct feasibility studies where commercially available medical devices are used and the interaction between the medical device and body is being studied non-invasively in healthy normal volunteers.

Question:
If data are not to be submitted to the FDA, does 21 CFR Part 11 apply to our electronic data records?

Thank you so much. Please do not hesitate to contact me with any questions you may have.

With kindest regards,

[redacted]