From: OC GCP Questions
To: [redacted]
Subject: Question regarding 21 CFR Part 11
Date: Friday, November 21, 2014 8:40:57 AM

Good morning --

There is no information on non-patient related documents. I would say if the documents under question are for the review and archival of electronic source data in/for an FDA-regulated clinical investigation, they should be Part 11 compliant.

Kind regards,

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

From: [redacted]
Sent: Thursday, November 20, 2014 3:10 PM
To: OC GCP Questions
Subject: RE: Question regarding 21 CFR Part 11

The type of data that I am looking to store electronically is not data capture systems or EMR-related information. Which is where I'm getting stuck on, as all the documents seem to talk about these types of systems that hold patient data. I'm wondering if there is any regulations or information sheets on non-patients related documents.
[redacted]

From: OC GCP Questions [mailto:gcp.questions@fda.hhs.gov]
Sent: Thursday, November 20, 2014 1:07 PM
To: [redacted]
Subject: Question regarding 21 CFR Part 11

Good afternoon –

An electronic data capture system for FDA-regulated studies should be Part 11 compliant. However, please see the information on EMRs below. 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 .

FDA's Draft Guidance for Industry – Electronic Source Data in Clinical Investigations found at 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.

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, November 20, 2014 10:58 AM
To: OC GCP Questions
Subject: Question regarding 21 CFR Part 11

I have a question regarding 21 CFR Part 11. Reading through this regulation and the Guidance Document (dated May 2007), it would seem that this guidance is meant for patient data and medical records.

I am in the process of working out an electronic document storage process for our regulatory documents (things like lab and IVRS manuals, copies of blank forms, correspondences, newsletters,

contact sheets, protocols, investigators brochures, etc), and wondering if storage of these types of documents need to fully comply with Part 11.

The system that our hospital uses is backed up daily, secured with username/password, and I feel that it would be a good way to keep things electronically, but it doesn't track all changes to documents like an EMR system. I'm wondering if keeping our regulatory documents in this type of system would go against Part 11, or if Part 11 is meant to be for patient data / medical records, and these types of documents are outside of this regulation.

Thank you for any help or advice that you can give.
[redacted]