From: OC GCP Questions
To: [redacted]
Subject: IRB records and Part 11
Date: Thursday, May 10, 2018 7:04:00 AM
Attachments: [redacted]

Good morning –

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 (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

www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070266.

FDA's Draft Guidance for Industry - Electronic Source Data in Clinical Investigations found at

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

www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126953.pdf

Kind regards,

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U.S. FOOD & DRUG ADMINISTRATION

From: [redacted]
Sent: Wednesday, May 09, 2018 4:28 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: IRB records and Part 11

Hi
If the IRB uses an e system to track reviews and store approval documents, is it required to be part 11 compliant?

Sincerely