From: OC GCP Questions
To: [redacted]
Subject: EDC
Date: Wednesday, March 27, 2019 8:36:24 AM
Attachments: [redacted]

Good morning –

There is no FDA requirement that a study use electronic data capture. Sponsors can decide whether to use electronic data capture for their studies or not and may spell that out as part of their protocol. Below are links to various FDA guidance documents related to implementation of Part 11 requirements and electronic records:

Our eSource Guidance:

www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM328691.pdf

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

How to handle the issue you describe is really a company decision. FDA does not have specific guidance on requesting data outside of the EDC.

Kind regards,

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

FDA U.S. FOOD & DRUG ADMINISTRATION

From: [redacted]
Sent: Tuesday, March 26, 2019 3:02 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: EDC

Hi,
I would like to know if a sponsor can request data from the investigator site instead of the accessing the EDC.

[redacted]