

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,

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This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

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.

