From: OC GCP Questions
To: [redacted]
Subject: Part 11 Question
Date: Wednesday, April 24, 2019 11:44:14 AM

Good morning –

Please send your email to the Center for Drugs (CDER), Office of Medical Policy (OMP) at CDEROMP@fda.hhs.gov as they are the experts on electronic records in clinical trials and Part 11.

The guidances listed below might be helpful to you.

Part 11 -Electronic Records -

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

Computerized Systems Used in Clinical Investigations -

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

Electronic Source Data in Clinical Investigations -

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

Kind regards,

The OGCP Group

From: [redacted]
Sent: Monday, April 22, 2019 2:39 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Cc: [redacted]
Subject: Part 11 Question

Hello,

Would it be compliant with 21 CFR Part 11 to have a consent form stored in a non-Part 11 compliant system, but signed with compliant software such as AdobeSign or DocuSign? Or is it only compliant if the consent form is both stored and signed in a Part 11 compliant system?

Thanks so much,

[redacted]