From: OC GCP Questions
To: [redacted]
Subject: Question
Date: Monday, November 30, 2015 6:27:16 AM

Good morning –

FDA's regulations do not actually refer to "regulatory binders" but rather to the records that need to be maintained. Although binders provide a way to organize and maintain records, there is no requirement to use them. That said please see the guidance documents below that discuss electronic files.

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

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: Wednesday, November 25, 2015 10:36 AM
To: OC GCP Questions
Subject: Question

Good Morning,

I have been looking on the FDA website to see if I we can go Electronic with our Regulatory Binders.
In Clinical research both for Case History studies as well as Investigational New Drug studies (IND).
My understanding was that IND study should have a hard copy Regulatory Binder.
To avoid keeping paper binders and go Electronic with the Reg Binder is there a Guidance out ?
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