

From: OC GCP Questions
To: [REDACTED]
Subject: Part 11 Compliance for IRB Electronic Record System
Date: Tuesday, August 29, 2017 12:19:00 PM

Good afternoon –

IRB electronic records would be subject to Part 11 compliance. Please see the guidance documents below.

Part 11, Electronic Records –

<https://www.fda.gov/downloads/regulatoryinformation/guidances/ucm125125.pdf>

Use of Electronic Informed Consent –

<https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM436811.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

Draft guidance on Informed consent -

www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM405006.pdf

Kind regards,

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From: [REDACTED]
Sent: Monday, August 28, 2017 3:05 PM
To: OC GCP Questions
Subject: Part 11 Compliance for IRB Electronic Record System

Hello,

What is the scope of applicability of 21 CFR Part 11 requirements for an electronic system utilized by an IRB to manage human subject research protocols throughout the project lifecycle?

Thank you very much.