

From: OC GCP Questions
To: [REDACTED]
Subject: Part 11 and IRB Records
Date: Wednesday, July 05, 2017 8:28:00 AM
Attachments: [REDACTED]

Good morning --

Yes, the 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Draft guidance on Informed consent

<https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM405006.pdf>

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: Thursday, June 29, 2017 5:25 PM
To: OC GCP Questions
Subject: Part 11 and IRB Records

Dear FDA,

I am writing to ask about this section of the regulation from 21 CFR Part 11. Does this mean that an institution that uses an electronic data base to upload pdf documents and track reviews of its IRBs is subject to the section below? When I read the record keeping requirements in, for example 21 cfr312, I don't see IRB records called out.

his part applies to records in electronic form that are created, modified,

maintained, archived, retrieved, or transmitted, under any records requirements set forth in agency regulations. This part also applies to electronic records submitted to the agency under requirements of the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, even if such records are not specifically identified in agency regulations.

Any guidance you and provide would be most appreciated. I looked for this question on your compilation of FDA GCP questions but couldn't find it.

Most sincerely,

A large black rectangular redaction box covering the signature and name of the sender. A small horizontal black bar extends from the right side of the box.