

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: SOPS- Signature Pages
Date: Friday, April 10, 2015 11:46:35 AM

Good morning --

Many institutions and sites are going to a fully electronic record system. It appears that the situation you describe in your email may not conflict with FDA regulatory requirements. It is not necessary to keep hard copies if the original files can be accessed electronically. However, if the protocol requires hard copies, whatever is specified in the protocol would be necessary. The regulations do not specifically address signing or dating of documents by the clinical investigator and or study staff. That said, sites therefore have flexibility in how they handle documents by creating standard operating procedures at their site.

The guidances listed below might be helpful to you.

Part 11 –Electronic Records --

<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126953.pdf>

Computerized Systems Used in Clinical Investigations –

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070266.pdf>

Electronic Source Data in Clinical Investigations –

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM328691.pdf>

This document includes information related to the creation and maintenance of electronic case report forms (eCRF). It describes an electronic medical record (EMR) as a possible data originator for an eCRF. However, section IV. of the document states that, although adequate controls need to be in place to ensure confidence in the reliability, quality and integrity of electronic source data, performance standards for EMRs may be regulated by other authorities and FDA does not intend to assess compliance of EMRs with part 11.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov for additional questions.

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: Friday, April 10, 2015 10:37 AM
To: OC GCP Questions
Subject: SOPS- Signature Pages

Office of GCP,

When a sponsor develops SOPs, Policies and other procedural documentation for its organization the documents typically contain a signature page. Signed SOPs/policies are typically stored electronically so that the staff of the sponsor can easily access the documents. If a sponsor develops an SOP/policy; obtains a wet-ink signature on the SOP from the approvers; scans the signed document into an electronic system, PDFs the document, and store the document electronically to allow staff accessibility, does the sponsor need to maintain the original wet-ink signed SOP/policy? Or can the sponsor destroy the wet-ink signed document and consider the electronically stored version the official document.

Thank you in advance for any insights you can provide.

