From: OC GCP Questions
To: [redacted]
Subject: SOPS- Signature Pages
Date: Tuesday, April 21, 2015 11:10:53 AM

Good morning –

I suspect the requirements would be the same. However, I am not as familiar with GMPs as with GCPs. You might need to send your question to the Center for Drugs (CDER) at druginfo@fda.hhs.gov. Additionally, please see FDA's web pages on GMPs. You might find some helpful information here.

Manufacturing > Questions and Answers on Current Good Manufacturing Practices (CGMP) for Drugs

Manufacturing > Drug Applications and Current Good Manufacturing Practice (CGMP) Regulations

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Monday, April 20, 2015 12:10 PM
To: OC GCP Questions
Subject: RE: SOPS- Signature Pages

Doreen,

As follow up to my previous question would your answer apply to GMP SOPs? Meaning if a sponsor develops GMP SOPs, the SOPs are signed by approvers, then scanned and stored electronically for employee access do the original hard copy signed SOPs needed to be kept or can the hard copy documents be destroyed and the electronic version maintained?

Thanks
[redacted]

From: OC GCP Questions [mailto:gcp.questions@fda.hhs.gov]
Sent: Friday, April 10, 2015 11:47 AM
To: [redacted]
Subject: SOPS- Signature Pages

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 and 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,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

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.

[redacted]