From: OC GCP Questions
To: [redacted]
Subject: Electronic Trial Master File and Regulatory Document Question
Date: Wednesday, February 07, 2018 11:46:00 AM
Attachments: [redacted]

Good morning –

If the CRO is operating as the sponsor then the CRO can maintain the original wet signature. Again, the sponsor and/or CRO should have established SOPs that describe who is handling/storing what documents.

Kind regards,

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

From: [redacted]
Sent: Wednesday, February 07, 2018 9:58 AM
To: OC GCP Questions <gcp.questions@fda.hhs.gov>
Subject: Fw: Electronic Trial Master File and Regulatory Document Question

Good day. Thank you for the answer below; however, the signature that I am questioning is a wet ink signature from a pen and not an electronic signature.

Thanks,
[redacted]

On Tuesday, February 6, 2018 12:38 PM, OC GCP Questions <gcp.questions@fda.hhs.gov> wrote:

Good afternoon –

You sent a similar question attached above.

There are no restrictions on which documents are maintained electronically or signed with e-signatures. If

a site were to have a bioresearch monitoring (BIMO) inspection, the FDA investigator would look for the site's procedures for validating e-signatures if they are used and determine if they were followed since there are no specific procedures identified in the regulations.

Again, FDA regulations do not address your specific question, therefore, sites and sponsors have flexibility in how they handle documents. You might wish to consider developing standard operating procedures (SOPs) for wet signature use and who is required to maintain them. The SOP that you develop might include instructions that documents how the original document with the wet signature will be obtained.

You might want to review the links below.

Guidance on Electronic Records, Electronic Signatures, link below.
www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126953.pdf

Electronic Source Data in Clinical Investigations -

www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM328691.pdf

Kind regards,

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

From: [redacted]
Sent: Thursday, February 01, 2018 3:30 PM
To: OC GCP Questions <gcp.questions@fda.hhs.gov>
Subject: Electronic Trial Master File and Regulatory Document Question

Good day. If regulatory documents are maintained in an electronic master file, is it a requirement that the original "wet ink" copies be maintained? Or if the regulatory documents are maintained in an electronic master file, should the CRO or the sponsor maintain the wet ink original documents?

Thanks,

[redacted]