From: OC GCP Questions
To: [redacted]
Subject: Requirement to Retain Documents with Wet Ink Signatures
Date: Friday, January 24, 2014 11:41:15 AM

Good morning –

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.

I've listed below a few FDA guidance documents that you may find helpful in answering your question:

FDA's Guidance for Industry – Computerized Systems Used in Clinical Investigations found at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070266.pdf

FDA's Draft Guidance for Industry – Electronic Source Data in Clinical Investigations found at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM328691.pdf

FDA's Guidance for Industry -- Part 11, Electronic Records; Electronic Signatures --Scope and Application found at http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126953.pdf

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

Kind regards,

Doreen M. Kezer, MSN
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Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [Redacted]
Sent: Friday, January 24, 2014 8:44 AM
To: OC GCP Questions
Subject: Requirement to Retain Documents with Wet Ink Signatures

Hello FDA Representative,

Our company has recently implemented an eTMF system which is Part 11 compliant. Our understanding is that In general, an electronic image of a document with a wet signature is legally valid and can be retained electronically. Knowing this, during an inspection, would the FDA look for certain documents to still be retained w/a wet ink signatures? For example, the Form FDA 1572 – the Agency has always looked for the wet ink signature of this document to be retained in the paper TMF. If the

1572 is now stored electronically in a Part 11 compliant eTMF system, is there a requirement that it be retained in paper?

Any advice would be greatly appreciated.

Thank you,

[Redacted]