

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: Electronic Signatures and Wet Ink Signatures on Same Document
Date: Wednesday, May 20, 2015 11:35:37 AM

Good morning –

FDA regulations are not that specific with regard to electronic signatures. The scenario you describe may not conflict with FDA regulations. Additionally 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 questions:

FDA's Guidance for Industry – Part 11, Electronic Records; Electronic Signatures – Scope and Application found at
<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072322.pdf>

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FDA's Draft Guidance for Industry – Electronic Source Data in Clinical Investigations found at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>

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have 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: Tuesday, May 19, 2015 3:36 PM
To: OC GCP Questions
Subject: Electronic Signatures and Wet Ink Signatures on Same Document

Hello - [REDACTED]

Would combining wet ink signatures and electronic signatures on the same document violate 21 CFR Part 11.70?

If a wet ink signature is appended to a document that is electronically signed, then would you agree that would break the electronic signature linkage to the document?

If a procedure existed that stated that an electronic signature can be applied to a document that has a wet ink signature, would that be sufficient to ensure that both signatures are appropriately linked to the original document?

Would greatly appreciate your input!

