From: OC GCP Questions
To: [redacted]
Subject: FDA 1572 - Electronic Signatures
Date: Tuesday, October 14, 2014 11:53:25 AM

Good morning –

Please see the guidance document link below. Part 11, Electronic Records; Electronic Signatures –Scope and Application

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm072322.pdf

It explains in detail what is considered an acceptable electronic signature.

A few other guidance documents that might be helpful to you are linked below.

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

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

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

Kind regards,

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Office of the Commissioner, FDA

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, October 14, 2014 11:14 AM
To: OC GCP Questions
Cc: [redacted]
Subject: FDA 1572 - Electronic Signatures

Good morning,

After reading the Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs –

FAQs Statement of Investigators (Form FDA 1572), I was curious as to the following question.

On page 10, question 18 it states, “The completed form must be signed and dated by the investigator (either by hand or using an acceptable electronic method).” Can you elaborate on what is considered an ‘acceptable electronic method’? We are considering moving to an electronic signatures process/software and wanted to confirm this before doing so.

Please advise at your earliest convenience.

Thank you,

[redacted]