From: OC GCP Questions
To: [redacted]
Subject: Electronic Signatures on Essential Study Documents
Date: Wednesday, July 13, 2016 9:31:00 AM
[redacted] [redacted]

Good morning --

This is what we had said in the past regarding electronic signatures.

A digital signature is a sub-set of electronic signature technology as both terms are defined in 21 CFR Part 11:

Digital signature means an electronic signature based upon cryptographic methods of originator authentication, computed by using a set of rules and a set of parameters such that the identity of the signer and the integrity of the data can be verified. 21 CFR 11.3(b)(5).

Electronic signature means a computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature. 21 CFR 11.3(b)(7).

FDA does not have a preference for digital or electronic signatures; both are valid if the regulatory requirements and expectations are satisfied.

21 CFR Part 11, Subpart C, establishes the following requirements: Signature/record linking (21 CFR 11.70), electronic signature components and controls (21 CFR 11.200), and controls for identification codes/passwords (21 CFR 11.300). Any records with electronic signatures that are maintained or submitted to FDA will be required to comply with these electronic signature requirements.

Generally, there is no FDA regulatory requirement that signatures for required records and reports be kept on paper or in a digital/electronic format, as long as they are accurate, complete, and current.

FDA's Guidance for Industry - Part 11, Electronic Records; Electronic Signatures - Scope and Application, Aug. 2003 (Part 11 Guidance), outlines expectations for persons who have chosen to maintain records or submit information to FDA in an electronic form. See www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072322.pdf. As you know, the Part 11 Guidance describes FDA's enforcement discretion policy regarding the following 21 CFR Part 11 provisions: (1) audit trails, (2) validation, (3) copies, and (4) retention of electronic records; subsequently, FDA is reliant upon enforcement of the predicate rules in 21 CFR Parts 312 and 812, pertaining to accurate and complete paper records, since the FDA regulatory requirements apply equally to both paper and electronic records.

The electronic signatures provision of 21 CFR Part 11, Subpart C, however, still applies and is being enforced.

Although it is not electronic signature specific, we recommend that you also review the Guidance for Industry - Computerized Systems Used in Clinical Investigations, May 2007, which outlines FDA's recommendations for the use of computers used to collect and manage clinical trial data, including discussions on user IDs/encrypted passwords, training, audit trails, and establishing SOPs. See www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070266.pdf.

In summary, there is no regulatory requirement that establishes whether signatures on records or information submitted to FDA must be in paper or in an electronic format. If a Sponsor chooses to maintain records or submit information to FDA in an electronic form, the electronic signatures provision of 21 CFR Part 11, Subpart C will apply: Signature/record linking, electronic signature components and controls, and controls for identification codes/passwords. Under this provision, there is no agency

preference for digital versus electronic signatures.

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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Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Tuesday, July 12, 2016 1:14 PM
To: OC GCP Questions
Subject: Electronic Signatures on Essential Study Documents

Hello,

I have a question in regards to the use of Electronic signatures on essential study documents.

Are there any essential study documents, if signed electronically by a 21 CFR Part 11 system, that the FDA would not consider as acceptable? Could all essential study documents be signed electronically? For example, the 1572, protocol signature page, Financial Disclosure, Investigator brochure acknowledgement page, etc.

Could these electronically signed essential study documents be used in lieu of original "wet-ink" paper records during an inspection?

Are flattened digital signatures with the printed name of the signer, date and time of when the signature was executed, and reason for the signature be acceptable on these essential study documents?

Thank you so much!

Best Regards,