From: OC GCP Questions
To: [redacted]
Subject: Informed Consent Signature
Date: Tuesday, September 09, 2014 1:39:08 PM

Good afternoon –

This is what our IT experts in the Center for Drugs (CDER) have said in the past regarding electronic informed consents.

The FDA regulatory requirements for Informed Consent, found in 21 CFR Part 50, do not explicitly prohibit having: "…the subject "sign" electronically and then have the option to print out a scanned version of the signature…" Further, as outline in FDA's Final Guidance for Industry on Part 11, Electronic Records; Electronic Signatures — Scope and Application, FDA does not intend to exercise enforcement on Electronic signatures.

Additionally, FDA recently issued a *draft* guidance on informed consent. Electronic signatures are address at the bottom of page 16 and the top of page 17.

http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM405006.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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Office of Good Clinical Practice

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.

-----Original Message-----
From: [redacted]
Sent: Tuesday, September 09, 2014 11:48 AM
To: OC GCP Questions
Subject: Informed Consent Signature

Will the agency accept electronic signatures for study coordinator and subject on the informed consent form?