From: OC GCP Questions
To: [redacted]
Subject: FDA 1572 - signature
Date: Friday, March 10, 2017 12:44:00 PM
Attachments: [redacted]

Good morning –

Please FDA's 1572 guidance below.
https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf It states --

18. How should the 1572 be completed?
The 1572 on FDA's website may be completed by typing the information directly into the fillable form and printing the completed form. Alternatively, it is acceptable to print the blank form from FDA's website and hand-write or type the information onto the form. Typed forms are preferable because they are usually more legible. The completed form must be signed and dated by the investigator (either by hand or using an acceptable electronic method).

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

FDA U.S. FOOD & DRUG ADMINISTRATION

From: [redacted]
Sent: Friday, March 10, 2017 10:40 AM
To: OC GCP Questions
Subject: FDA 1572 - signature

Dear Sir or Madam

Would you please direct me if the FDA 1572 form can be signed electronically by the investigator or should the electronic signature be compliant with regulation 21CFR part 11 ?

Thank you kindly,

[redacted]

[redacted]

[redacted]