From: OC GCP Questions
To: [redacted]
Subject: form 1572 question (19 Aug 2019)
Date: Monday, August 19, 2019 1:02:26 PM

Good afternoon –

Please see FDA's 1572 guidance. https://www.fda.gov/media/78830/download

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

From: [redacted]
Sent: Monday, August 19, 2019 9:26 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>; CDER DRUG INFO <DRUGINFO@fda.hhs.gov>
Subject: form 1572 question (19 Aug 2019)

Hello,

Can you please clarify if it is required for the PI to hand write the date of his signature of the FDA 1572 Form. This question is being asked because the 1572 smart form allows for a typed date to be inserted.

Please advise if I can be of more assistance.

Kindest regards,

[redacted]