From: OC GCP Questions
To: [redacted]
Subject: Fda Form 1572
Date: Monday, August 19, 2019 12:55:56 PM
Attachments: [redacted]

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: Sunday, August 18, 2019 6:15 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Fda Form 1572

Good Afternoon,

There has been some questions surrounding the FDA Form 1572, does this form need a wet ink signature and are there any particular regulations specific to US and ROW?

Kr,
[redacted]

[redacted]

[redacted]

[redacted]