From: OC GCP Questions
To: [redacted]
Subject: Fillable FDA form 1572 (digitally signed)
Date: Friday, May 19, 2017 11:20:00 AM
Attachments: [redacted]

Good morning –

Please see FDA's guidance on the 1572 form. (Link below)

https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf

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).

I suggest that you follow the 1572 guidance.

Kind regards,

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

From: [redacted]
Sent: Friday, May 19, 2017 2:15 AM
To: OC GCP Questions
Subject: Fillable FDA form 1572 (digitally signed)

Dear Sir/Ma'am,

This is regarding recently published draft guidance by the agency "Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications Guidance for Industry" in April 2017.

We just want to enlighten the Point# L (FDA Forms) *"Electronic submissions must include only FDA fillable forms (e.g., 1571 or 356h) and electronic signatures to enable automated processing of the submission. The FDA forms are available at*

http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm. *Scanned images of FDA forms will not be accepted."*

Since this point has given examples of 1571 or 356h. Since "FDA 1572 The Statement of Investigator" form is also fillable FDA form So Does this FDA form 1572 would also come under above said requirement and may need to submit with during the Clinical study report (digitally singed by Principle Investigator)?

We would request your response that will help us to comply the requirements by the agency in streamline manner. Thank you in advance for your time

Thank you

[redacted]

[redacted]