

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: Question re: Statement of Investigator Form
Date: Thursday, March 17, 2016 6:18:38 AM

Good morning –

The FDA guidance document (link below) states --

<http://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 hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
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.

From: [REDACTED]
Sent: Wednesday, March 16, 2016 4:02 PM
To: OC GCP Questions
Subject: Question re: Statement of Investigator Form

Hello,

I would like to know if the FDA 1572 (Statement of Investigator) form must be typed or can it be filled out by hand?

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]