

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: eSignatures on 1572
Date: Wednesday, February 17, 2016 9:26:23 AM

Good morning –

Please see the 1572 guidance document (link below). Yes the 1572 form can be signed electronically by any acceptable method.

<http://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**).*

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

Kind regards,

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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: Tuesday, February 16, 2016 11:30 AM
To: OC GCP Questions
Subject: eSignatures on 1572

Hello,

I am interested in the FDA's opinion in regards to signing the Form FDA 1572 electronically. I know the FDA supports electronic records and signatures but there seems to be a rumor in our industry that the 1572 cannot be signed with an electronic signature because the FDA will not accept it. Is this true or can electronic signatures be used?

Also, if electronic signatures are acceptable on the 1572, is there a preferred method that the FDA

accepts? For example, some electronic signatures will appear on the signature line that is provided on the document. Other electronic signatures may appear as an attached document that cannot be removed or altered. I'm sure there are other methods of signing electronically but is there an ideal method for FDA acceptance?

I appreciate your guidance. Thank you.

[REDACTED]

[REDACTED]

[REDACTED]