From: OC GCP Questions

To:

Subject: FW: Handwriting and typed on the same 1572

Date: Thursday, February 19, 2015 12:20:47 PM

## Good afternoon -

What you describe below does not appear to go against FDA regulations.

Kind regards,

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

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From:

Sent: Thursday, February 19, 2015 11:32 AM

To: OC GCP Questions

Subject: Handwriting and typed on the same 1572

Hi,

I just wanted to get confirmation on something minor.

A site has completed a 1572 electronically but after printing it out, they added the country and zip code to section 1 by hand.

The guidance says:

## 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 wanted to confirm how literally that was to be taken. Can we EITHER complete it by typing the information into the form OR print it out and hand-write or type the information into the form or is a mix of directly entered and hand-writing acceptable?