

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: Form FDA 1572 - Compliance Clarifications
Date: Monday, May 11, 2015 11:10:00 AM

Good morning –

I am not aware that abbreviations on the form are not acceptable. The form must be completed in a legible manner. Please see the 1572 document guidance link below.

<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 information.

Kind regards,

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Office of Good Clinical Practice
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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: Monday, May 11, 2015 10:22 AM
To: OC GCP Questions
Subject: Form FDA 1572 - Compliance Clarifications

Good morning,

I have recently taken on the role of compliance assistant over multiple research units at a not-for-profit teaching hospital. Prior to this I was the regulatory document specialist for one of the specific units. It was always my understanding in my previous roll, that you are not supposed to abbreviate within the Form 1572 (ie: Street as St.).

Can you provide some clarification on whether abbreviations on this form are acceptable and to what degree. I have reviewed several guidelines and recommendations and have not found a clear answer.

Your assistance is much appreciated.

[REDACTED]