From: OC GCP Questions
To: [redacted]
Subject: Form 1572 Signature Requirements - Wet Ink or pdf
Date: Friday, October 02, 2015 8:48:33 AM

Good morning –

A scanned copy of 1572 is acceptable as long as it is a certified copy. Please see below.

You might find FDA's 1572 form guidance helpful. Please see the link below.
http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf

The sponsor should obtain the original signed document for the 1572. Per the instructions on the 1572 form, the clinical investigator is instructed to:

5. FORWARD THE COMPLETED FORM AND OTHER DOCUMENTS BEING PROVIDED TO THE SPONSOR. The sponsor will incorporate this information along with other technical data into an Investigational New Drug Application (IND). INVESTIGATORS SHOULD NOT SEND THIS FORM DIRECTLY TO THE FOOD AND DRUG ADMINISTRATION.

Additionally, if it is decided to have a certified copy substitute for the original, it would be desirable to have a "standard operating procedure" (SOP) describing how such copies would be made, verified, and documented. The person who certifies the copy as an accurate and complete representation of the original, having all of the same attributes and information should be the same person who actually made the copy from the original. Certification should be accomplished by having the person who makes the copy, sign or initial and date the copy to indicate it meets the requirements of a certified copy as described above. This should be described in the SOP and can be accomplished by initialing and dating each copy or by initialing and dating a document certifying copies in bulk. Whichever method is used the SOP should describe the procedure. (There are many ways to accomplish this, and the procedures described above are only suggested examples.)

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

From: [redacted]
Sent: Thursday, October 01, 2015 1:43 PM
To: OC GCP Questions
Subject: Form 1572 Signature Requirements - Wet Ink or pdf

Hi,

I couldn’t find specific guidance on whether or not the sponsor would be required to keep the wet ink signature copies of the 1572 or if a scanned pdf sent in from the site would be adequate for the sponsor’s files.

Is there a requirement that the sponsor maintain the wet ink signature versions of the 1572?

Any guidance would be most helpful,

Thanks,

[redacted]