

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: Requirement to Retain Documents with Wet Ink Signatures
Date: Friday, January 31, 2014 5:44:04 AM

Good morning –

I consulted our IT experts in the Center for Drugs (CDER) for further clarification. Please see their response below.

As indicated in FDA's Final Guidance on Computerized Systems Used in Clinical Investigations, the term certified copy is defined as: "A certified copy is a copy of original information that has been verified, as indicated by a dated signature, as an exact copy having all of the same attributes and information as the original."

Further, the term original data is defined in the guidance as: "For the purpose of this guidance, original data are those values that represent the first recording of study data. FDA is allowing original documents and the original data recorded on those documents to be replaced by copies provided the copies are identical and have been verified as such (see FDA Compliance Policy Guide # 7150.13).

See: <http://www.fda.gov/ohrms/dockets/98fr/04d-0440-gdl0002.pdf>

As such, certified copies may be used to replace original data or source records.

It appears from your case scenario that you identified in your e-mail below, that the electronic image (pdf) may be considered, in your case, a certified copy which could replace the original paper source record with the wet ink signature (provided you followed the recommendations for a certified copy as outlined in the final guidance).

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: ~~OFYXUM~~YXQ
Sent: Tuesday, January 28, 2014 3:54 PM
To: OC GCP Questions
Subject: RE: Requirement to Retain Documents with Wet Ink Signatures

Thank you very much for your response. I am not sure if you understood my question exactly. I am more concerned as to when we take a paper document that has a wet signature and we scan it and now it is an electronic image (pdf) of the paper, are there any requirements that we need to keep the paper that contains the wet-ink signature in addition to having it in the eTMF as an electronic image? The document doesn't contain an e-signature, it is just an electronic copy of a wet-signature.

I hope that clarifies my question. Thank you very much for your time.