From: OC GCP Questions
To: [redacted]
Subject: RE: Wet ink paper documents in eTMF
Date: Thursday, September 15, 2016 3:12:54 PM

[redacted]:

If a 'certified copy' of the original document is created, it can be used as a trial record in lieu of the original document. The following advisement was previously given that may be useful:

If your TMF file is simply composed of scanned copies of paper documents and/or manual creation of electronic documents (using word processing software) and you intend to use the electronic copy in lieu of the paper source copy (i.e., you intend to destroy the paper source copy), we recommend the following:

- You should have a process in place to certify that (1) the scanned electronic copy is an accurate representation of the original paper document and (2) electronic copies of electronic originals have the same information, including data that describe the context, content, and structure of the data as the original. The electronic copy should be certified with a dated signature and you should have written procedures to ensure consistency in the certification process.

- The scanned electronic copy should retain the audit trail of the data that are recorded on the paper copy (any additions, deletions, or alterations of source information that had been made). For electronic copies that vary in terms of their ability to be modified, it would be important to have audit trails or other physical, logical, or procedural security measures in place to ensure the trustworthiness and reliability of the electronic copy.

For more information, please see Guidance for Industry: Electronic Source Data in Clinical Investigations. Available at:
http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm328691.pdf

Sincerely,
Bridget A. Foltz, MS, MT(ASCP)
Policy Analyst, Office of Good Clinical Practice
Office of the Commissioner, Food and Drug Administration

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, September 13, 2016 1:23 PM
To: OC GCP Questions
Subject: RE: Wet ink paper documents in eTMF

Thanks for your response, but I want to be sure that I understand correctly.

Please see my example:

- I have an original signed 1572 from a clinical site and I scan and upload a copy in the electronic TMF
- Since the eTMF has an audit trail, every document has a date stamp and a record of the person who uploaded it
- Once the document is in the eTMF, I open it to be sure that it is legible and that it is looks like the original
- **Now that the document is available in the eTMF, I can shred the original**

It's the last bullet point that I want to confirm.

Thanks,

[redacted]

From: OC GCP Questions [mailto:gcp.questions@fda.hhs.gov]
Sent: Friday, September 09, 2016 3:42 PM
To: [redacted]
Subject: RE: Wet ink paper documents in eTMF

Dear [redacted],

We frequently receive questions regarding electronic records. First, FDA permits the interchangeable use of electronic and paper records for the archiving and protection of records provided that record keeping and retention requirements are met (see §§ 56.115, 312.57, 312.62, and 812.140). You are not required to have paper back-ups of electronic source data. Electronic source data refers to data initially recorded in electronic format. When electronic source data are used, the electronic system and records must comply with 21 CFR part 11.

If you intend use an electronic scanned copy in lieu of the paper source data (i.e., destroy the paper source data), the electronic system and records must comply with 21 CFR part 11. FDA accepts the electronic scanned copies of documents without the original paper records, provided that there is a process in place to certify that the electronic copy is an accurate representation of the original paper document. 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. The person who makes the copy should sign or initial and date the copy to indicate it meets the requirements of a certified copy as described above. IRBs, sponsors and other regulated entities should have written procedures to ensure consistency in the certification process.

The following guidance documents might be helpful to you.

Part 11 -Electronic Records -

www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126953.pdf

Computerized Systems Used in Clinical Investigations -

www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070266.pdf

Electronic Source Data in Clinical Investigations -

www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM328691.pdf

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

Sincerely,

Bridget A. Foltz, MS, MT(ASCP)
Policy Analyst, Office of Good Clinical Practice
Office of the Commissioner, Food and Drug Administration

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From: [redacted]
Sent: Friday, September 09, 2016 1:18 PM
To: OC GCP Questions
Subject: Wet ink paper documents in eTMF

Once a document with a wet ink signature is scanned and posted in the eTMF, is it a requirement to keep the original in a paper file?

[redacted]