From: OC GCP Questions
To: [redacted]
Subject: scanned document as primary source record
Date: Thursday, April 14, 2016 7:09:51 AM
[redacted]

Good morning –

It appears that the printout of documents from the electronic system or at the time of scanning the original document so the initial and date appears on the scanned document may not conflict with FDA regulations.

As noted previously, the use of a certified copy generally applies to situations where original records are copied to a different media (e.g., electronic records such as a pdf file) for archiving purposes and the originals are destroyed. If it is decided to have a certified copy substitute for the original, it would be desirable to have an 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.

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, April 14, 2016 3:10 AM
To: OC GCP Questions
Subject: RE: scanned document as primary source record

Hello Doreen
Opps documents now attached
Kind Regards
[redacted]

[redacted]

[redacted]

From: [redacted]
Sent: Thursday, April 14, 2016 5:07 PM
To: gcp.questions@fda.hhs.gov
Subject: scanned document as primary source record

Hello Doreen.
[redacted] from [redacted] has forwarded your response (email dated 24 March 2016) to me regarding the scanned medical record being used as the sourced original document.

[redacted] is transitioning from paper based medical records to electronic medical records. Part of the process is the scanning of paper medical records. Later in the year, the original paper document will be destroyed after an intense verification process of the scanned document to the original paper document. The scanned document will become the original source document. The verifying process has not commenced and therefore paper records are available.

Through this transition [redacted] needs to remain compliant with the legislative and regulatory requirements and clinical trial requirements for data.

[redacted] policy directive regarding hybrid health care record (attached) contains the procedure for verifying paper to the scanned document and the paper record is destroyed in accordance with [redacted] State Records Act 1998. The bases of the [redacted] policy is the State Records Authority of [redacted] general retention and disposal authority (attached) that outline destruction of original documents after copying is permitted and the key points are:

- authentic, complete and accessible copies have been made
- copies are official record of business
- read only controls on network servers
- maintain through system documentation including description of any image enhancement techniques
- use of security controls such as access passwords and audit trials to prevent alteration of the copies

In your email you state "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." Does that apply to printout of documents from the electronic system or at the time of scanning the original document so the initial and date appears on the scanned document?

Please confirm if the scanned document will be accepted as the original source document as outlined in the [redacted] policy for the acceptance of data from clinical trials for regulatory purposes. If you require any further information please contact me on [redacted].

I look forward to hearing from you.

Kind Regards
[redacted]

Cheers
[redacted]

[redacted]