From: OC GCP Questions
To: [redacted]
Subject: RE: Destruction Process/Certified Copies of Source Documents
Date: Monday, January 28, 2019 12:21:00 PM
Attachments: [redacted]

Dear [redacted],
The term "certified copy" is defined in FDA's Final Guidance Computerized Systems Used in Clinical Investigations 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." Please see: https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm070266.pdf.

The use of certified copies generally applies to situations where original records are copied to a different media for archiving purposes and the originals are destroyed. However, 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. The SOP should describe the procedure, whichever method is used. (There are many ways to accomplish this, and the procedures described above are only suggested examples.)

Please also see the guidance on *Part 11 -Electronic Records* https://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm125125.pdf and the *Guidance for Industry - Electronic Source Data in Clinical Investigations* http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm328691.pdf

I hope this information is helpful to you. If you need further assistance, please feel free to contact the GCP mailbox at gcp.questions@fda.hhs.gov .

Best regards,

Sheila

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[redacted]

From: [redacted]
Sent: Monday, December 31, 2018 11:00 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Destruction Process/Certified Copies of Source Documents

Hi,

Our site recently switched to electronic medical records and I am hoping that you can provide me with information so that we can come up with an SOP on Certified Copies of Source Documents. Once the study is closed, we would like to destroy the original source with wet ink. According to our CTMS, we are allowed to do so as long as we have a SOP in place stating this. Can you provide me with information to support this?

Kind Regards,

[redacted]