From:	OC GCP Questions
To:	[redacted]
[redacted]	[redacted]
Subject:	destruction of original source documents after certify copying original documents
Date:	Monday, June 17, 2019 11:03:02 AM
Attachments:	[redacted]

Good morning -

Our OGCP office is frequently asked whether investigators/sites may store/archive study records by converting paper documents into an electronic format; in essence, creating certified copies of source documents.

FDA's draft guidance for industry entitled, "Use of Electronic Records and Electronic Signatures in Clinical Investigations Under 21 CFR Part 11 –
Questions and Answers" - https://www.fda.gov/media/105557/download provides recommendations to sponsors, clinical investigators, IRBs, CROs, and other interested parties on the use of electronic records and electronic signatures under part 11 in clinical investigations of medical products. Appendix II of this draft guidance defines certified copy as:

Certified Copy is a copy (paper or electronic) 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.

I think question #6 in the draft guidance is responsive to your question (copied below):

Q6. Can sponsors and other regulated entities use and retain electronic copies of source documents in place of the original paper source documents?

Yes. FDA permits the interchangeable use of electronic records and paper records for the archiving and protection of records provided that recordkeeping and retention requirements are met (see 21 CFR 56.115, 312.57, 312.62, and 812.140). If the sponsor or other regulated entity intends to use an electronic copy in place of the paper source data (i.e., intends to destroy the paper source data), then part 11 regulations would apply to the electronic system used to create the copy (see §§ 11.10 and 11.30)). A process should be in place to certify that the electronic copy is an accurate representation of the original paper document. The copy of the original record should be verified as having all of the same attributes and information as the original record and certified as indicated by a dated signature. Sponsors and other regulated entities should have written procedures to ensure consistency in the certification process.

In addition, some electronic copies vary in terms of their ability to be modified. For electronic copies in which the records are modifiable, it would be important to have audit trails in place to ensure the trustworthiness and reliability of the electronic copy. Also, as noted earlier, 21 CFR 11.10 and 11.30 require physical, logical, and procedural controls designed to ensure the authenticity and integrity of electronic records.

Although this guidance is still draft, OGCP has responded to many public inquiries about scanning paper ICFs to an electronic format in this manner. As noted in the draft guidance, if it is decided to have a certified copy substitute for the original, a process should be in place to certify that the electronic copy is an accurate representation of the original paper document (e.g., a Standard Operating Procedure (SOP) describing how such copies would be made, verified, and documented).

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. The process should be described in an 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. NOTE: There may be multiple ways to accomplish this, and the procedures described here are only suggested examples.

Appendix I of the draft guidance document also has some good references to other guidance documents with applicable recommendation that may be helpful to your colleagues.

In the situation you describe and based on information from FDA guidance on the subject, it appears that destruction of the hard copy is acceptable, however, to be sure you should consult the sponsor.

The second scenario, since it is Part 11 compliant, it appears that the signature on the tablet would be acceptable. Again, please review the guidance referenced above.

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, June 13, 2019 5:27 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Cc: [redacted]
Subject: destruction of original source documents after certify copying original documentsdocuments

Good Afternoon,

A question has arisen during a recent monitoring visit regarding certified copies of paper records. Several times study information is collected on paper forms. It is then certified copied using a process that is described in our SOP's that the certified copy is an exact original of the paper record and then uploaded into our electronic files. We were recently instructed that the original paper records should not be destroyed rather should be kept in addition to our certified copy that was uploaded to our electronic files. Once the document has been certified copied. Can the original paper form be destroyed?

Another question is we collect data using a tablet rather than paper. A handwritten signature is collected on the tablet with the use of a stylus. The study data is then maintained in a FDA part 11 compliant system, Is the handwritten signature equivalent to one collected on paper?

I look forward to your guidance.